"Effectiveness of warm compression at lumbo-sacral region on intensity of labor pain during first stage of labor among parturient women admitted in tertiary care hospital, Bhopal: A Randomized Controlled Trial"

Dissertation

Submitted to the Faculty of Nursing

ALL INDIA INSTITUTE OF MEDICAL SCIENCES, BHOPAL

In partial fulfilment of the requirement for the degree of M.Sc. in Obstetric and Gynaecological Nursing

By

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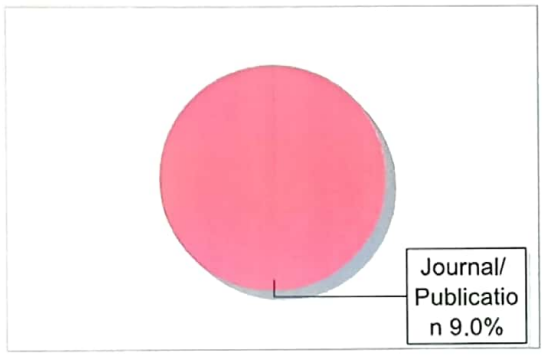

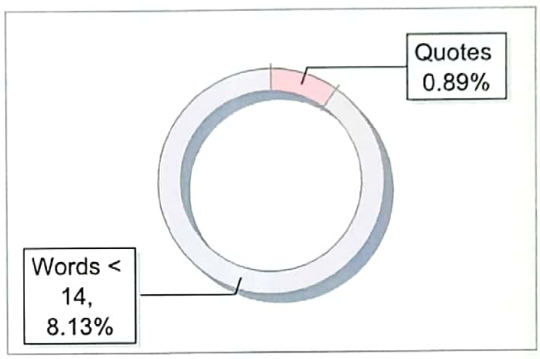

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AIIMS, Bhopal Institutional Human Ethics Committee- Student Research (IHEC-SR) in its 7th meeting held on 22nd February 2023 discussed your proposal titled **"Effectiveness of warm compression at lumbo-sacral region on intensity of labor pain during first stage of labor among parturient women admitted in tertiary care hospital, Bhopal: a randomized controlled trial"** and evaluated it for suitability for your dissertation as required for fulfilment of MSc (Nursing).

Following members attended the meeting:

1. Prof. D. K. Pal, Former HoD Community Medicine, GMC, Bhopal……Chairperson
2. Prof. Rajnish Joshi, Professor of General Medicine, AIIMS, Bhopal……..Member
3. Prof. Amit Agrawal, Professor of Neurosurgery, AIIMS, Bhopal……..Member
4. Dr. Sunita Athawale, Professor of Anatomy, AIIMS, Bhopal……..Member
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7. Dr. Ankur Joshi, Assoc. Professor of CFM, AIIMS, Bhopal……...Member
8. Mr. Trivesh Goswami, Law Officer, AIIMS Bhopal,…..……..Member
9. Dr. Shashank Purwar, Professor of Microbiology, AIIMS, Bhopal…..…Member Secretary

The decision of the committee is as follows:

The AIIMS, Bhopal IHEC-SR approves your research protocol. All research related activities must begin only after the date of this approval. The validity of this approval is till two years from the date of issuance. Please submit a closure report / renewal request before expiration of the validity for this approval.

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No one who achieve success does so, without acknowledging the help of others. The wise and confident acknowledge this help with gratitude.

-Alfred North Whitehead

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Date:

Place Sharmistha Patel

Abstract

TITLE OF THE STUDY

"Effectiveness of warm compression at lumbo-sacral region on intensity of labor pain during first stage of labor among parturient women admitted in tertiary care hospital, Bhopal: a randomized controlled trial"

Introduction: Labor pain is the most basic and fundamental of life's experience. It is a complex, subjective and multidimensional response to sensory stimuli generated during parturition. It is severe and difficult to be tolerated by every woman. There are many non-pharmacological therapies available for the relief of labor pain like: Aromatherapy, Music therapy, Acupressure, Yoga, Breathing exercise etc. The present study was undertaken to assess the effectiveness of warm compression which is very simple, easy and convenient method in clinical setting, at lumbo-sacral region on intensity of labor pain during first stage of labor.

Method: A Randomized control trial was carried out at the labor room of tertiary care hospital, Bhopal (All India Institute Of Medical Sciences, Bhopal) from October – November 2023. A total 50 Parturient women without any pregnancy related complications were recruited through convenient sampling technique and allocated randomly into experimental(n=25) and control group(n=25) by using sequentially numbered opaque sealed envelope (SNOSE). Experimental group received Warm compression at lumbo-sacral region which was given twice for 20 minutes with an interval of 30 minutes in 1^{st} stage of labour, whereas the control group received routine obstetrical care. Effectiveness of intervention was measured by assessing the pain intensity before and immediately after 1^{st} , 2^{nd} warm compression and 30 mins after 2^{nd} warm compression by using visual analogue scale (VAS).

Result: Both the groups were homogenous in the characteristics in terms of Sociodemographic and clinical variable ($p>0.05$). Study result revealed that immediately after 2^{nd} warm compression and after 30 minute of 2^{nd} warm compression the intensity of labor pain in experimental group was significantly lower than control group respectively ($t_{(24)}= 2.75$, $p<0.05$; $t_{(24)}=6.73$,$p<0.05$) . whereas, there was no significant difference found in pre intervention pain intensity and immediately after 1^{st} warm compression pain intensity score between the group.

Conclusion – Warm compression is an easy and convenient method to decrease the pain intensity among parturient women in 1^{st} stage of labor. It helps women to participate fully in the birthing process, to earn continuous caregiver support, to feel cared for and comforted, and have a more positive overall satisfactory birthing experience.

Trial registration -CTRI/2023/10/058413

Keyword- Labor Pain, first stage of labor, active stage, intensity of labor pain Warm compression, heat therapy, Parturient women, non-pharmacological method for labor pain, Primipara

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10.	Participant Information sheet (English)
11.	Participant Information sheet (Hindi)
12.	Informed Consent form
13.	Master data sheet
14.	Calibration certificate of the lotion thermometer.

LIST OF ABBREVIATIONS

S.NO	ABBREVIATIONS	EXPANSION
1.	AIIMS	All India Institute of Medical Sciences
2.	CVI	Content Validity Index
3.	f	Frequency
4.	HOD	Head of Department
5.	IHEC-SR	Institutional Human Ethics Committee- Student Research
6.	K-S Test	Kolmogorov-Smirnov Test
7.	LOP	Letter of Permission
8.	M.Sc.	Masters of Sciences
9.	N	Sample Size
10.	VAS	Visual analogue scale
11.	PG	Post Graduate
12.	CI	Confidence interval
13.	SCVI (Average)	Scale content validity index
14.	df	Degree of freedom
15.	n	Sample size

LIST OF SYMBOLS

S.NO	SYMBOLS	EXPANSION
1.	%	Percentage
2.	>	More than
3.	<	Less than
4.	≥	Equal to or more than
5.	H0	Null Hypotheses
6.	H1	Research Hypotheses
7.	p	Level of significance
8.	d	Precision
9.	&	And
10.	=	Equal to

INTRODUCTION

Background of the study

"When a woman gives birth. She has pain because her time has come. But when the child is born, she no longer remembers her distress because of her joy that child has been born into the world" (John 16:21)

Childbirth is a multifaceted experience for women, encompassing physical, psychological, emotional, social, and cultural dimensions.[1] Childbirth's mechanism and physiology encompass a natural, spontaneous process it has been performed physiologically for many years.[2]

There are three stages of labor, first stage starts from true labor pain to full dilation of the cervix. Again, first stage consists three phase latent, active and transitional. In 1st stage contraction are more progressive, painful ,longer and stronger. The second stage is start from full dilatation to expulsion of the baby. and the third stage take place from birth to expulsion of the placenta. [3]

Labor is the active process of delivering a fetus and is characterized by regular, painful uterine contractions which increase in frequency and intensity. The intensity of labor pain increases with greater cervical dilatation and correlates well with the intensity, duration and frequency of uterine contractions.[3]Pain is the most common and unavoidable component of natural childbirth.[2]

Labor pain is complex, subjective, multidimensional response to sensory stimuli generated during parturition.[4] Labor pain is not associated with pathology but with the most basic and fundamental of life ‘s experience. [5]

Pain in labor is universal and is accepted. Labor pain is viewed as a consequence of imbalance between two energy entities. Thus, for a woman in labor, her labor experience may depend on how well her physical, psychological, and spiritual energies are balanced and harmonized [6].

Fear of pain and anxiety is correlated with intense labor pain, and a woman’s confidence in her ability to cope with labor pain is strongly associated with less pain. [4] The affective component of pain is greater in the early stage of labor in nulliparous women than in multiparous women, and it tends to decrease in both groups in the second stage of Labor. [7]

Labor pain consists of two main components: visceral and somatic. The cervix plays a central role in both the initial and later stages of labor. Visceral pain is present in the early first stage and the second stage of childbirth. During contractions, pressure is exerted on the cervix, leading to stretching and expansion. This process activates excitatory nociceptive afferents, which innervate the endocervix and lower segment spanning from T10 to L1, corresponding to the transmission of pain signals from the lower abdomen and pelvic region. Understanding the anatomical aspects of labor pain is crucial for effective pain management during childbirth, utilizing various strategies to address both visceral and somatic components for an improved birthing experience.[8]

Alongside the visceral pain previously stated, somatic pain also appears in the latter part of the first phase of labor and continues into the second. It arises from sensory afferents innervating the vaginal surface, cervix, and perineum. Stretching, distension, ischemia,

and possible injury (such as tearing or iatrogenic causes) affecting the pelvic floor, perineum, and vagina are the causes of this kind of pain. Somatic symptoms appear when the fetus descends, Uterine contraction become Stronger, Rhythmic in Active stage.[8]

Pain during labor is a complex experience influenced by multiple factors. These factors can be categorized into physical and biological, sociocultural, and psychological dimensions. In terms of physical and biological factors, elements such as a woman's age, parity, body mass index, position during birth, and oxytocin levels play a role in shaping the perception and acceptance of pain. For instance, younger or older women may have different experiences, and the number of previous childbirths can impact how pain is perceived. Additionally, body composition, birthing positions, and hormonal influences, such as oxytocin, contribute to the overall experience. Sociocultural factors, including cultural, religious, and ethnic aspects, are crucial in understanding the perception of labor pain. Different cultural beliefs and practices can significantly influence how individuals interpret and cope with pain. In some cases, these influences may lead to unique and sometimes extreme interpretations of pain. Psychological factors also play a substantial role. Emotions, past painful experiences, level of preparedness for childbirth, environmental factors, attachment patterns, and personality traits all contribute to modifying the perception of pain during labor.[8,9] The emotional state of the individual, coupled with their unique life experiences and psychological characteristics, adds another layer of complexity to the overall experience of pain during childbirth.[8,9]

Pregnant women who experience extreme pain it lead towards increased level of worry and anxiety, which causes their catecholamine secretion to rise. The release of catecholamines causes the pelvic muscles to strain, which in turn creates resistance to the uterus's repulsive pull as well as the force that pregnant women exert. If this situation is

allowed to worsen, labor becomes more painful. As a result, the American College of Obstetricians and Gynecologists and the American Society of Anesthesiologists have recognized that a maternal demand for pain relief is an adequate medical indication for treatment to relieve labor.[10]

During the labor pain some women is demanding for cesarean section because she can't tolerate labor pain. , 59% of the causes of cesarean section are due to fear of normal labor pain, which indicates that fear of normal labor pain can lead to an increase in cesarean section rates in pregnant women. [11]

Advances in anesthesia during the last part of the 20th century resulted in the widespread use of spinal blocks and epidurals as regional analgesics for labor pain.[12]

The pharmacological pain method was becoming gold standard in high income and developing country because of their pain reducing nature. [13] In recent decades, opioids like fentanyl and morphine have gained widespread usage for their pain-alleviating properties, even though they do not eliminate pain entirely. [14] Despite their effectiveness, pharmacological pain management methods (PPM) carry various side effects and risks like, epidurals analgesia cause hypotension, fever and an increased likelihood of requiring assisted delivery.[15]

They have also been associated with prolonged labor. Opioid induce nausea in neonate if admitted soon.[16,17] Pain is the norm of childbirth, and using drugs to alleviate it may lead to a loss of crucial feedback for laboring women, potentially resulting in extended labor or increased intervention. Additionally, some PPMs restrict a woman's motility and her ability to adopt different positions for comfort, causing distress. The lack of control over pain is highlighted as a significant concern for women during childbirth. In essence, the passage emphasizes the effectiveness of pharmacological pain management methods

but also draws attention to the associated risks and challenges, advocating for a careful consideration of the balance between pain relief and potential adverse effects.

The interest in and utilization of Complementary and Alternative Medicine (CAM) has been on the rise, especially among women in their reproductive years. Nearly half of women in this demographic report using CAM. This trend extends to labor, as evidenced by a recent survey representing the Australian population, where a substantial 74% of women reported using CAM during childbirth. Various analgesic CAM techniques are employed, falling into different categories. These include massage techniques, the use of a birth ball, application of heat, acupressure, transcutaneous electrical nerve stimulation (TENS), and various "mind-body" interventions such as music, dancing, distraction techniques, prayer, and even virtual reality. The prevalence of CAM use during labor suggests a growing interest in alternative approaches to managing pain and promoting well-being during the childbirth process.[18]

The application of warm compression is a straightforward and safe method with no adverse effects on both the mother and the fetus. It serves to assist the mother by reducing labor pain and enhancing maternal satisfaction. The mechanism involves the stimulation of heat receptors in the skin and deeper tissues. Various impulses generated by this stimulation neutralize each other at the spinal cord level, effectively closing the gate and consequently hindering neural impulses from reaching the brain. This process contributes to pain relief during labor.

Need of the study

All women expect that she gives birth her child naturally. It is beautiful experience during naturally childbirth she need more psychological and emotional support and therapeutic touch. [19]

Labor pain is Difficult to tolerate by women during labor she exhausted with more intense pain and can't bear down she also demanding for operative delivery and labor analgesia. According to NFHS 5 phase data the cesarean section rate in India in public sector is 47.4 %and in private sector 14.3%.there are several conditions for performing caesarean section in which labor pain is also one factor.[20]

Safe practice of labor analgesia in parturient applies to obstetricians and anesthesiologists. In India, practice of labor analgesia is wavering. Barely 23% of parturient accept labor analgesia according to the previous survey done in Delhi and Chennai. [21,22]

Mostly parturient women are satisfying by non- pharmacological method about 90%.there are many non- pharmacological therapies like aromatherapy, music therapy, cold compression, heat therapy, acupressure , yoga, breathing exercise. [23]

When comparing nonpharmacological techniques with pharmaceutical techniques that manage pain adequately, there are a number of benefits. Nonpharmacological treatments do not slow down the labor process, provide no risks of unpleasant effects or allergies, and are safe for both the mother and the fetus. One of the goals of fundamental nursing reduce the labor pain during childbirth. One of the nonpharmacological intervention techniques that can help women in labor feel less pain is topical therapy, like as massage or the use of heat packs.[10]

The adoption of Non-Pharmacological Pain Management (NPPM) methods faces obstacles such as limited availability, a lack of understanding, cultural expectations, and diverse individual preferences. Overcoming these challenges necessitates targeted approaches, including the improvement of healthcare infrastructure, increased education and awareness, alignment with cultural norms, and the customization of information to cater to individual choices. Additionally, the undertaking of expansive, standardized research studies is crucial for gaining insights into the efficacy and potential long-term implications associated with NPPM techniques. [24]

The effects of massage and heat applications on pain in childbirth have been explained with the gate control theory. [25]

Durumes Aysenue et.al carried out study on effects of massage and hot-pack applications in the first stage of labor on perceptions of labor pain and duration of delivery. The study result revealed that the massage and hot-pack applications shortened the durations of the active and transition phases of labor. The massage and hot-pack applications also reduced perceptions of pain in the active and transition phases. Mean VAS scores of the massage and hot-pack application groups were lower than those of the control group ($p<0.001$).[25]

Massage and heat applications are thought to reduce the sensation of pain by activating the large-diameter fibers that transmit physical sensations, thereby inhibiting or overriding the small-diameter fibers that transmit pain messages. Warm compresses or massages during labor oxygenate the area to which they are applied and remove waste products from that area as a result of vasodilation of the peripheral blood vessels. They also increase local circulation, reduce ischemia and increase the release of endorphins. These applications help stimulate the sympathetic nervous

system, relax skeletal muscles and relieve bone pain5. The perception of labor pain is weakened by heat as endorphin levels and blood circulation increase, muscles relax and cellular metabolites that stimulate pain impulses are inhibited.[25]

Dastjred fatemah et .al conducted RCT on effect of the infrared belt and hot water bag on intensity of labor pain among primipara. The study result was the mean score of pain intensity was significantly lower in the two intervention groups compared to the control group ($P < 0.001$). The mean pain intensity was significantly lower in the infrared belt group than in the hot water bag group ($P < 0.001$).[26]

Warm compression is very simple method.it is effective to mother and not harmful to child. The warm compress during labor can maintain the components of the vascular system in a state of vasodilatation so that blood circulation to the pelvic muscles become homeostatic and can reduce anxiety and fear and adapt to pain during labor.[4]Warm compress therapy has been shown to increases the mother's ability to tolerate pain during childbirth due to the effects of heat. it worked base on gate control theory of pain.[8]

Hence, investigator used warm cotton cloth, it is easily available in every health care setting. It is non-invasive and non -pharmacological method . in which investigator apply two warm compressions between every 30 minutes interval. And provide relief to mother.

Research problem

"A Study to assess the effectiveness of warm compression at lumbo- sacral region on intensity of labor pain among Parturient women admitted in tertiary care hospital, Bhopal"

Research questions

Is warm compression effective at lumbo-sacral region on intensity of labor pain during first stage of labor ?

Aim

The aim of the study is to assess the effectiveness of warm compression on lumbo-sacral region in terms of labor pain

Objectives

1. To assess the intensity of labor pain among parturient women in first stage of labor in control group.
2. To assess the intensity of labor pain among parturient women in first stage of labor before and after warm compression at lumbo-sacral region in experimental group.
3. To assess the effectiveness of warm compression at lumbo -sacral region on intensity of labor pain during first stage of labor among parturient women
4. To find association between intensity of labor pain with selected demographic & clinical variable.

Hypothesis

H0: There is no significant difference in intensity of labor pain among Experimental and control group at 0.05 significance level.A Measured by Visual analogue scale

H1: There is significant difference in intensity of labor pain among Experimental and control group at 0.05 significance level. A Measured by Visual analogue scale.

Operational definition

Warm compression : In this study, It refers to refers to A method of moist heat application using a clean cotton cloth (15cm length, 15 cm width, 1 cm thickness) soaked in warm water with temperature of 50 to 60 degree Celsius (122.0 f to 140.0 f) applied at lumbo-sacral region for 20 minutes

Effectiveness : In this study**,** It refers to outcome of the warm compression at lumbo - sacral region on Intensity of labor pain during first stage of labor among parturient women. It is measured by using Visual analogue scale.

Lumbo – sacral region : The lumbo-sacral region of the spine consists 5 lumber vertebra and the first sacral vertebra.

Intensity of labor pain : Pain during labor is caused by contraction of the muscle of the uterus and by pressure on the cervix it is subjective and measure by using visual analogue scale

First stage of labor: In this study**,** first stage of labor it started from the active phase in which dilatation of cervix reach to 4 cm and up to full dilatation.

Parturient : In this study it refers to a woman who is giving birth and completed 37 Week of gestation.

Delimitation

The study is only limited to parturient women admitted in AIIMS,Bhopal.

Conceptual framework

Polit and Hungler state that the conceptual framework is interrelated concepts on abstractions that are assembled together in some rational scheme by virtue of this relevance to a common scheme. It is a device that helps to stimulate research and the extension of knowledge by providing both direction and impetus. The present study was aimed at determining the effectiveness of warm compress at lumbo-sacral region on intensity of labour pain among parturient .

The conceptual framework for this study based on general system theory with Input, Process, Output and feedback, as introduced by Ludwing Von Bertalanffy. [27]

According this theory, a system is a group of elements that interact with one another in order to achieve the goal. An individual is a system because he or she receive input from the environment. This input when processed provides an output.

All living system are open, in that there is a continual exchange of matters, energy and information. The system is cyclical in nature and continuous to be so,as long as the four parts (Input,Process,Output and Feedback) keep interacting. If there is change in any of these parts there will be change in all the parts. Feedback from within the system or from the environmental providers information, which helps the system to determine whether it is meeting its goal or not.

INPUT : Input consist of information ,material or energy that enters the system. In the present study Input was parturient women with demographic and clinical characteristic.

PROCESS : After the input is absorbed by the system, it is processed in a way useful to the system. Here the Process refers In this model was provide warm compression to parturient women and effectiveness assessed by taking pre and posttest of both group by using Visual analogue scale.

OUTPUT: Output from system is energy ; matter of information disposed by the system as result of its process. In this study the output were depicted as follows:

Favorable outcome : Warm compress was effective method to reduce the labor pain in 1sta stage of labor among parturient women ,Positive effect.

Unfavorable outcome : Warm compression was ineffective method to reduce labor pain in 1st stage of labor among parturient women. Negative effect.

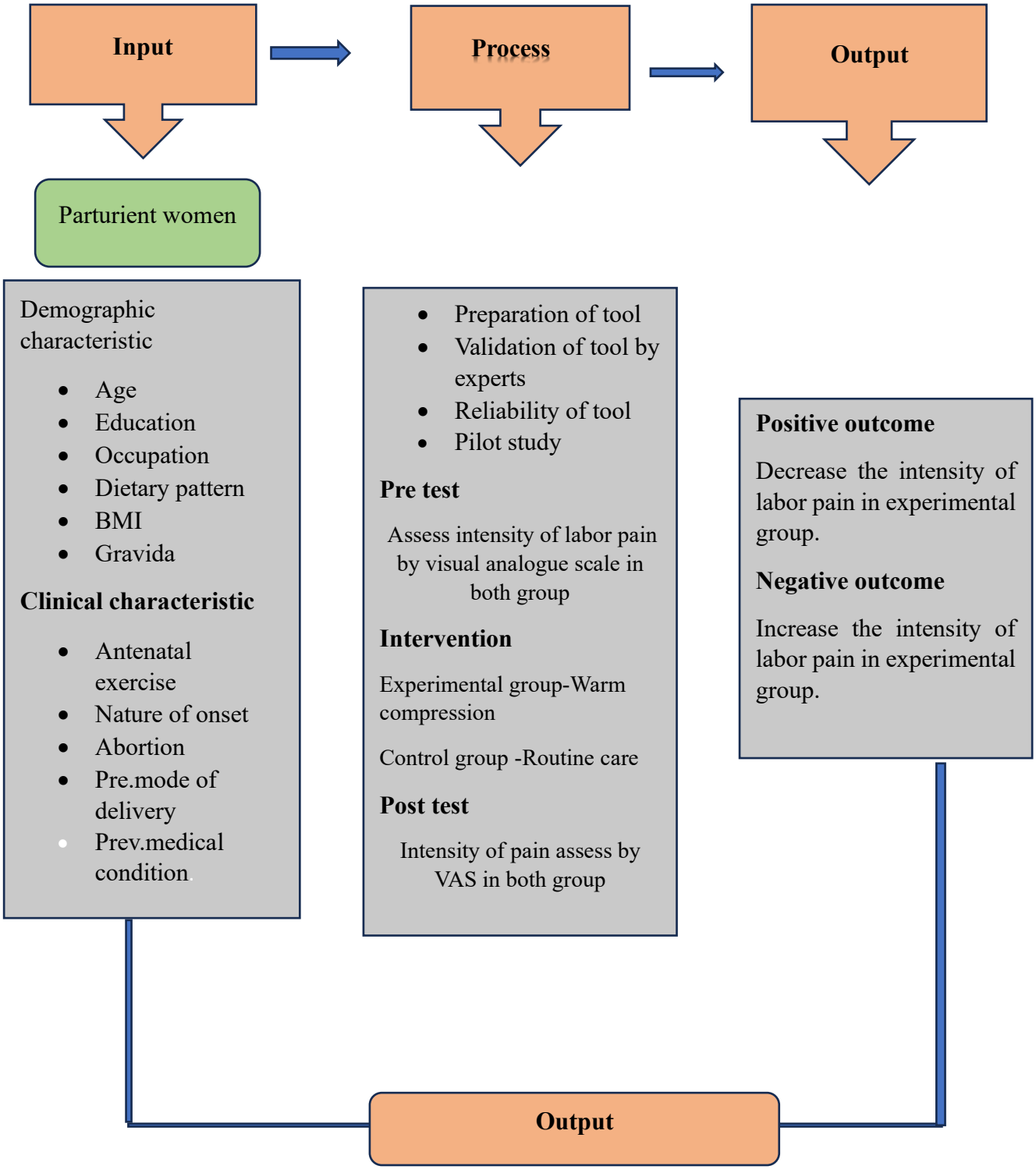

Fig 1: Conceptual framework

Summary :

This chapter dealt with the background of the study ,need of the study, research problem, research questions and Objectives of the study, research hypotheses, assumption, operational definition, delimitation and conceptual framework of the study. The next chapter includes Review of literature.

CHAPTER -II

REVIEW OF LITERATURE

The review of literature is a summary of different research on a topic of interest to put a research problem in context or to identify gaps and weakness in prior studies so as to justify new researches.[28] It is a summary of all the reviews from various research literatures related to the current study carried out by the researcher. It helps to discover what is already known about the research problem and what more has to be done. [29]

According to Abdellah and Levine, the material gathered in literature review should be included as a part of the research data, since it influences the problem and research. It is an assessment of a body of research that addresses a research question.[30] Burns and Grove defined it as an organized written presentation of what has been published on a topic by the scholars. It may also be defined as an account of what has been published by accredited scholars and researchers.[31]

The investigator carried out wide-ranging review on the research topic in order to gain understanding of the problem and to build the basis of the study.

Search Strategy

The investigator searched the electronic databases including Web of Science, PubMed, Cochrane Library, Google Scholar, Wiley online library, Science direct for the publications on non-pharmacological management of labor pain from the past 10 years. The searches were carried out using MeSH terms combined with Boolean operators in PubMed. The Boolean operators were used as – AND, OR, NOT such as “labor Pain ”

OR "Warm compression" AND "Parturient women " AND "labor" OR "non-pharmacological pain management "The extensive review of literature was done and the researches include articles with full text, abstracts, free full text, documents, clinical trial, meta-analysis, randomized controlled trial, systematic review and protocols. The keywords used were - Labor Pain, first stage of labor, active stage, intensity of labor pain Warm compression, heat therapy, Parturient women, non-pharmacological method for labor pain, Primipara

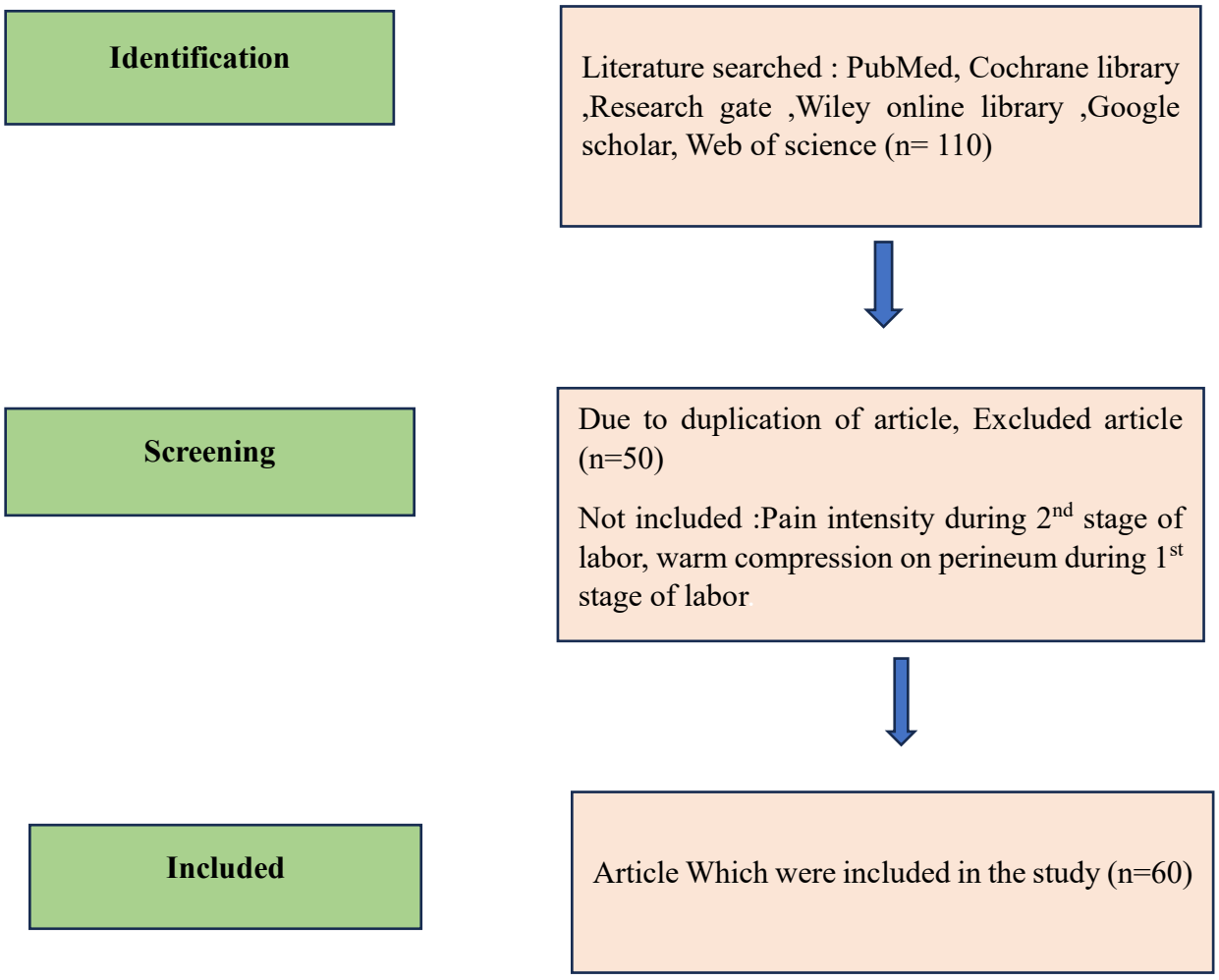
Identification
Literature searched : PubMed, Cochrane library ,Research gate ,Wiley online library ,Google scholar, Web of science (n= 110)
Screening
Due to duplication of article, Excluded article (n=50)
Not included :Pain intensity during 2nd stage of labor, warm compression on perineum during 1st stage of labor
Included
Article Which were included in the study (n=60)

Figure 2: Schematic reorientation of search strategy

The reviewed literature for the present study is presented under the following headings-

Section A:The literature related to nature and intensity of labor pain.

Section B:The literature related to Non pharmacological method for reliving labor pain.

Section C: The Literature related to effectiveness of warm compress on level of labor pain

Section A:The literature related to nature and intensity of labor pain

Labor pain intensity varies throughout the labor process, which consists of different stages. The mechanisms contributing to labor pain involve the rhythmic contractions of the uterine muscles, changes in the cervix, and the descent of the baby through the birth canal. The pain can range from mild and cramp-like in early labor to more intense and pressure-focused during active labor and the pushing stage. The intensity of labor pain is a highly variable and subjective aspect of childbirth. Influenced by factors such as individual pain thresholds, the nature of contractions, and the duration of labor, women experience a wide range of sensations during this process.

An evident suggested ,the nature of labor pain by the By Simona labor in year 2008,The intensity of labor pain corresponds closely with greater cervical dilatation and aligns with the intensity, duration, and frequency of uterine contractions, reflecting the complexity and subjectivity of the labor experience. Labor pain encompasses both visceral and somatic components, with the cervix playing a pivotal role in both the initial and later stages. Visceral pain is occurs during the early first stage and the second stage of childbirth. This type of pain occurs as pressure from uterine contractions is transmitted to the cervix, causing stretching and distension and activating excitatory nociceptive afferents that innervate the endocervix and lower segment from T10 – L1. Somatic pain, occurring in the late first stage and the second stage, is a result of afferents that innervate the vaginal surface of the cervix, perineum, and vagina. This pain arises due to stretching, distension, ischemia, and potential injury, such as tearing or iatrogenic harm to the pelvic floor, perineum, and vagina. It becomes more

pronounced during the active stage of labor when the uterus contracts more intensely and rhythmically during the descent of the fetus.[4]

An updated Literature review conducted In the year of 2019 on the nature of labor pain for better understanding. For the collection of literature investigators used search database like Medline, Cumulative index to nursing and Allied health literature and PsycINFO And select thirty-one papers. Finding of the study was labor pain is subjective, it is challenging, emotional and meaningful pain. The determinants and influence of labor pain was identified and categorized into the cognitive, social and environmental factor. It depends on women if she perceived pain as purposeful and productive ,safe and supporting birth environment it would be expected she would experience pain as non-threating and transformative life event.[32]

The Factor contribute the labor pain is also childbirth experience, it is evident by a comparative study conducted in Guangzhou, China with aim of assess the pain intensity and intrapartum analgesic consumption between primiparous and multiparous.it is conducted from February(2018) to August (2019).Sample size was 260 women who undergoing spontaneous or induced labor, including 163 multipara women ,97 primipara women. Sample recruited by using convenient sampling method . tool was used in this study was Demographic qustionnaries,Numerical rating scale, The Chinese version of the childbirth attitude questionaries and analgesic consumption measured by using analgesia pump. Data was collected and analyzed the study result was Multi para had more intense of labor pain{ 8.00 (8.00, 9.00)] than primiparas [8.00 (7.00, 8.00)].It indicated that Multipara had more intense of pain rather than primipara.

It is indicate the previous childbirth is also contributed factor on the intensity of labor pain but researcher were recommended to further explore more in this aspect.[33]

A cross sectional study was conducted in Mashhad (Iran) with aim of the determine the relationship between behavioral indicators during labor pain, severity of pain, and delivery duration. The sample size was 120 and it is selected by using convenient sampling method. the Labor Pain Coping Behavior Observation Form used as tool in this study. The study findings indicate that during labor, 16.2% of individuals exhibited undesirable behavioral indicators, 50% displayed acceptable behaviors, and 33.8% demonstrated desirable behaviors. A significant, inverse correlation ($p<0.001$ and $r=-0.450$) was observed between the severity of pain and behavioral indicators during labor. Higher mean scores of behavioral indicators were associated with shorter labor duration and reduced pain severity. In conclusion, the study suggests that women's behaviors during labor is key indicator for identify severity of pain ,emphasizing the importance of addressing these behaviors in clinical management for more favorable outcomes.[34]

A qualitative descriptive study was conducted to comprehend childbirth pain in Brazilian women, involving 21 participants. In-depth interviews were conducted for data collection, and thematic analysis was used for data interpretation. The results revealed that women with positive experiences required minimal support, displayed equilibrium, and expressed manageability of pain. In contrast, those with unfavorable experiences characterized pain as a threat and punishment, associated with negative emotions. [35]

Section B:The literature related to Non pharmacological method of reliving labor pain.

Non-pharmacological pain management strategies for labor pain play a crucial role in enhancing the overall birthing experience and promoting maternal well-being. While pharmaceutical interventions are commonly used but it is associated with side effect. On-pharmacological approaches offer additional options that are often safer and have fewer side effects.

As evidence suggest, The study conducted in Poland aimed to establish the effects of and compare pharmacological and non-pharmacological methods of labor pain relief. A total of 258 women participated in the study and were interviewed using a questionnaire and the visual analogue scale for pain. The participants were divided into six groups based on the chosen method of labor pain relief: epidural anesthesia (EA; n = 42), water immersion and water birth (WB; n = 40), nitrous oxide gas for pain control (G; n = 40), transcutaneous electrical nerve stimulation (TENS) (n = 50), multiple management (MM; n = 42), and no specific method (N; n = 44).The study findings revealed that The mean values of labor pain intensity were reported as 6.81 ± 2.26 during the first stage of labor, 7.86 ± 2.06 during the second stage, and 3.22 ± 2.46 during the third stage, There was no significant difference in pain levels between the epidural analgesia and gas groups during the first stage of labor ($p = 0.74$). However, epidural analgesia was found to reduce pain levels significantly during the second and third stages (both $p < 0.01$). The highest satisfaction level was reported in the water immersion group, with 95% (n = 38) of participants expressing satisfaction with this method.[36]

There were many non-pharmacological methods available to reduce labor pain A systematic review and metanalysis conducted to evaluate the effectiveness of non-pharmacological method to relieve labor pain. investigator included 63 study in this review, all study were randomized controlled trial. Search data base for the review was PubMed, Scopus were searched from inception to May 2021. Data analyzed through R version 3.5.157 using the tidyverse and metafor packages. The review was revealed that massage, birth ball, mind body relation, heat therapy Music therapy, acupressure ,dance therapy had significant effect on relieve labor pain. [18]

Gallo silva et al. conducted a study on sequentially application of non-pharmacological method to reduce labor pain .study design was randomized controlled trial. Eighty women are selected for this study in which 40 in experimental group and 40 in control group. Administered intervention was massage ,warm shower and Swiss ball exercise. Pain assessed by using visual analogue scale. Study result revealed that sequentially non-pharmacological reduce the labor pain from 4cm to beyond 7 cm of cervical dilation. [37]

Another evidence suggested, a systematic review conducted on non-pharmacological pain management in labor, In a study conducted between 2015 and 2020, researchers focused on women in the initial stage of childbirth labor, exploring three non-pharmacological interventions: hydrotherapy, therapeutic touch, and the use of birthing or peanut balls. The inclusion criteria involved peer-reviewed publications and primary sources within the last five years, sourced from databases like CINAHL plus with full text, MEDLINE with full text, and SocINDEX with full text. The study's results indicated that hydrotherapy, therapeutic touch, and the utilization of birthing or peanut

balls were found to be effective in reducing the sensation of pain in mothers during the first stage of labor. These findings suggest the potential implementation of these methods into current clinical practice to enhance maternal care.[38]

A qualitative study on nurse and midwife 's experience of using non-pharmacological intervention for labor pain management conducted in 2019 It was descriptive phenomenological study. sample size was 15.data collected by interview and analyzed by guided by the principles of coding by Bailey and the constant comparative approach to generate theme. Study result revealed that participant familiar with non-pharmacological method ,perceived benefit and barrier and use of this method like cold compress, hot compress, acupressure, breathing exercise.[39]

For the Access the services women and health care provider have knowledge related to non-pharmacological pain management for support this evident conducted a study on knowledge of non-pharmacological techniques for pain relief during childbirth. It was conducted in Brazil ,Total 171 women was included in this study ,the tool was used in this study were questionaries related to sociodemographic ,obstetrical characteristic and knowledge of non-pharmacological method .the study findings revealed that a total 96.6% women had knowledge at least one NPM, 87.1%women had knowledge regarding warm shower, 80.7% women had knowledge regarding birthing ball, 74.8% women had knowledge regarding birthing technique and multivariate analysis showed that women experiencing pain during pregnancy were more likely to be aware of using warm showers during labor (OR=2.64; 95% CI: 1.03–6.73).[40]

There are many factors contributing to utilization of the non-pharmacological labor pain relieve method like the respondents, clinical experience, individual preference,

attitude and knowledge this is evident by the study conducted in Ethiopia it is conducted in 2021 with cross sectional design total 270,000 participant were participated in this study. The obstetric care provider were study population in this study. Study result was the overall use of non-pharmacological methods for managing labor pain was found to be 59.3% (95% CI: 53.9–63.4). Among the study participants, 65.5% exhibited unfavorable attitudes toward these methods. Gender differences were noted, with females having a negative association compared to males (β= -0.420; 95% CI: -0.667, -0.173). Clinical experience also showed a negative association (β= -0.201; 95% CI: -0.268, -0.134). On the other hand, a positive association was observed with both the knowledge sum score (β = 0.227: 95% CI: 0.18, 0.247) and the attitude sum score (β= 0.376; 95% CI: 0.283, 0.47) related to non-pharmacological labor pain management. In summary, factors like gender, clinical experience, knowledge, and attitudes were significantly linked to the utilization of non-pharmacological methods for handling labor pain.[41]

The effectiveness of these methods varies from person to person, and a combination of strategies may be tailored to meet individual needs. In conclusion, incorporating non-pharmacological pain management techniques, such as relaxation exercises, breathing techniques, hydrotherapy, massage, and position changes, alongside medical interventions, can contribute to a holistic and patient-centered approach to labor pain management. These methods empower women to actively participate in their birthing process, fostering a sense of control and satisfaction. Additionally, the integration of non-pharmacological interventions may reduce the need for pharmacological pain relief, promoting a more natural and positive birth experience. However, it is essential

for healthcare providers to individualize care and provide adequate support, education, and resources to ensure the successful implementation of these strategies and enhance the overall childbirth experience.

Section C: The Literature related to effectiveness of warm compress on intensity labor pain.

A systematic review and meta-analysis conducted to assess the impact of heat therapy on pain intensity, duration of the first stage of labor, and APGAR Score. The study exclusively included randomized controlled trials published until October 2022, sourced from PubMed/Medline, Clinical key, Ovid discovery, and EMBASE. Out of 7,652 studies screened by investigators, 10 studies meeting the inclusion criteria were Selected. The pooled data analysis revealed significant effectiveness of heat therapy in reducing pain intensity during the first stage of labor, as indicated by a standard mean difference SMD=1.31 95% CI: -1.88 – -0.73; $p<0.001$.This finding suggests that heat therapy had a notable impact on alleviating pain during the specified stage of labor, based on the available randomized controlled trials up to October 2022.[23]

Another study conducted in year 2020 to evaluate the effectiveness of warm compression on lumbo-sacral region in terms of labor pain intensity and labor outcomes. In this study experimental design was used. Sample size was 88,Among them 44 nulliparous were in control group and 44 in experimental group. Numerical pain rating scale was used to assess the intensity of labor pain. After the statistical analysis findings was revealed that immediately after 1st ,2nd and 3rd warm compression intensity of labor pain in experimental group respectively (t= 3.20; P<

0.001; t =4.45; P< 0.001; t= 6.18; P< 0.001).it is lower than control group. so warm compression was effective in 1st stage of labor to relive labor pain.[42]

Another one study to evaluate the effectiveness of warm compresses on intensity of labor pain in primigravida mother in the first stage of active phase. The study design was quasi experimental design with total sample size 30.there were 15 participant in control group and 15 participant in experimental group. assessed the pain score by using the pain scale according to Bourbanis.data was collected and analyzed study result revealed that after the warm compression there were Mild pain(16.7%),Moderate pain (33.3%),Severe pain (26.7%),and very severe pain (23.3%).it is lower than control group. Moreover, a statistically significant difference (p-value = 0.00, <0.05) underscored the meaningful impact of warm compress intervention in diminishing labor pain intensity among primigravida mothers during the initial stage of the active phase.[43]

Another one study conducted on the effect of warm compress Bi-stage on pain strength in labor stages and after delivery. The study design was randomized controlled trial it was conducted in shiraz hospital from July 2012 march 2013 .It carried out on 150 participant women ,both groups had 75 sample. Study sample was selected through purposive sampling technique and used block randomization. Data was collected by using demographic, clinical and pregnancy period data questionnaires and an observation form including the labor stage information. Visual analogue scale used for assess pain level. There were found significant different in experimental and control group in the first stage ,second stage of labor and postpartum respectively(

p<0.002,p<0.001 ,p<0.001).so the conclusion was throughout the labor and postpartum warm compression was effective in reducing perineal pain.[44]

To Evaluate the effectiveness of massage and heat therapy on labor pain a comparative study conducted in year 2020. The study employed a quasi-experimental design with a sample size of 30 participants, where 15 received hot compress, and the other 15 received massage during the study. Pain levels were evaluated using the Visual Analogue Scale. The statistical analysis indicated no significant differences between the two interventions. Post-intervention scores showed a decrease in both groups compared to pre-test scores. Consequently, the findings suggest that both hot compress and massage have equivalent effects in reducing labor pain.[45]

A quasi-experimental study conducted in the year 2017 To Evaluate the effect of sacral warm compress on the level of pain during first stage of labor among Primigravida mother. Sampling technique used in this study was non-probability -purposive sampling technique. Sample size was 30. the data were collected by using Demographic sheet, FLACC Scale and numerical pain rating scale. The p value is<0.05 in posttest 1 in experimental group.it indicated that warm compression helps to reduce the labor pain in primigravida mothers.[46]

Lawot Isabel et.al conducted systematic review and metanalysis regarding effect of heat and cold therapy on intensity of labor pain and labor outcome.in this review includes randomized controlled trial and non-randomized controlled trial. Source of the ROL was PubMed-Medline, CINHAL Direct, Database .taken studies from 2011 to 2023 and quality of the study was assessed by JBI clinical appraisal. The review result was the heat and cold therapy were effective to reduce labor pain.[47]

A randomized controlled trial was conducted in Spain to evaluate the application of heat on lumber and suprapubic region in terms of reducing labor pain .study was conducted between September 2017 to a March 2018.total sample size was 135 childbearing women. heat applied by using the Elastic pelvic belt the study result revealed that before the intervention pain level higher in experimental group and lower in control group after heat therapy pain level reduced in experimental group compare to control group it indicated that warm compression was effective to reduce the labor pain. [48]

Research gap analysis :

The reviewed literature on intensity of labor pain ,non-pharmacological method to reduce labor pain and warm compression is useful method to reduce labor pain, But noticeable research gap persist in the integration and exploration of these aspect comprehensively. Mostly studies were found the immediately effectiveness of warm compression and there are more need to explore evidence regarding long term effectiveness of warm compression at lumbo- sacral region. Even majority of the researcher warm compression given by using pelvic belt, then heat pad ,hot water bag sometimes in clinical setting it is not available.

In current study pain intensity was measure immediately and after 30 minutes so it was indicated measure long term effect of warm compression.in this study used cotton cloth as warm compression it is convenient easily available ,and cost effective. So, anyone can used easily in clinical settings.

Summary :

This chapter dealt with wide range of literature reviewed in relation to the present study. The reviewed for the present study are classified under the following heading -The literature related to nature and intensity of labor pain. The literature related to Non pharmacological method and complementary therapy for reliving labor pain. Literature related to Literature related to effectiveness of warm compress on level of labor pain. Majority of the review revealed that warm compression was effective method to reliving labor pain ,Majority of the study focused on short term labor pain Relieve.

CHAPTER -III

MATERIALS AND METHODS

Introduction

Research methodology is a systematic theoretical analysis of the methods applied to any field of the study [28].it includes the strategies to be used to collect and analysis of the data according the research objectives. This chapter presents the research methodology ranging from research approach and design to target population and sampling method adopted in the study with the aim to determine the effectiveness of warm compression at lumbo-sacral region on intensity of labor pain during 1st stage of labor among parturient women. It also highlights the data collection methods, approaches and instruments used. Beside this, the chapter also presents the validity and reliability as component of the data analysis tools and the ethical consideration applied during the course of data collection.

Research Approach

The research approaches are the plans and procedures for research that extend the steps from broad assumptions to detailed methods of data collection, analysis, and interpretation.[28]

The present study Aimed at Assessing the effectiveness of warm compression at lumbo-sacral region on intensity of labor pain during 1st stage of labor among parturient women. Thus, a **quantitative approach** was found to be appropriate for the study.[49]

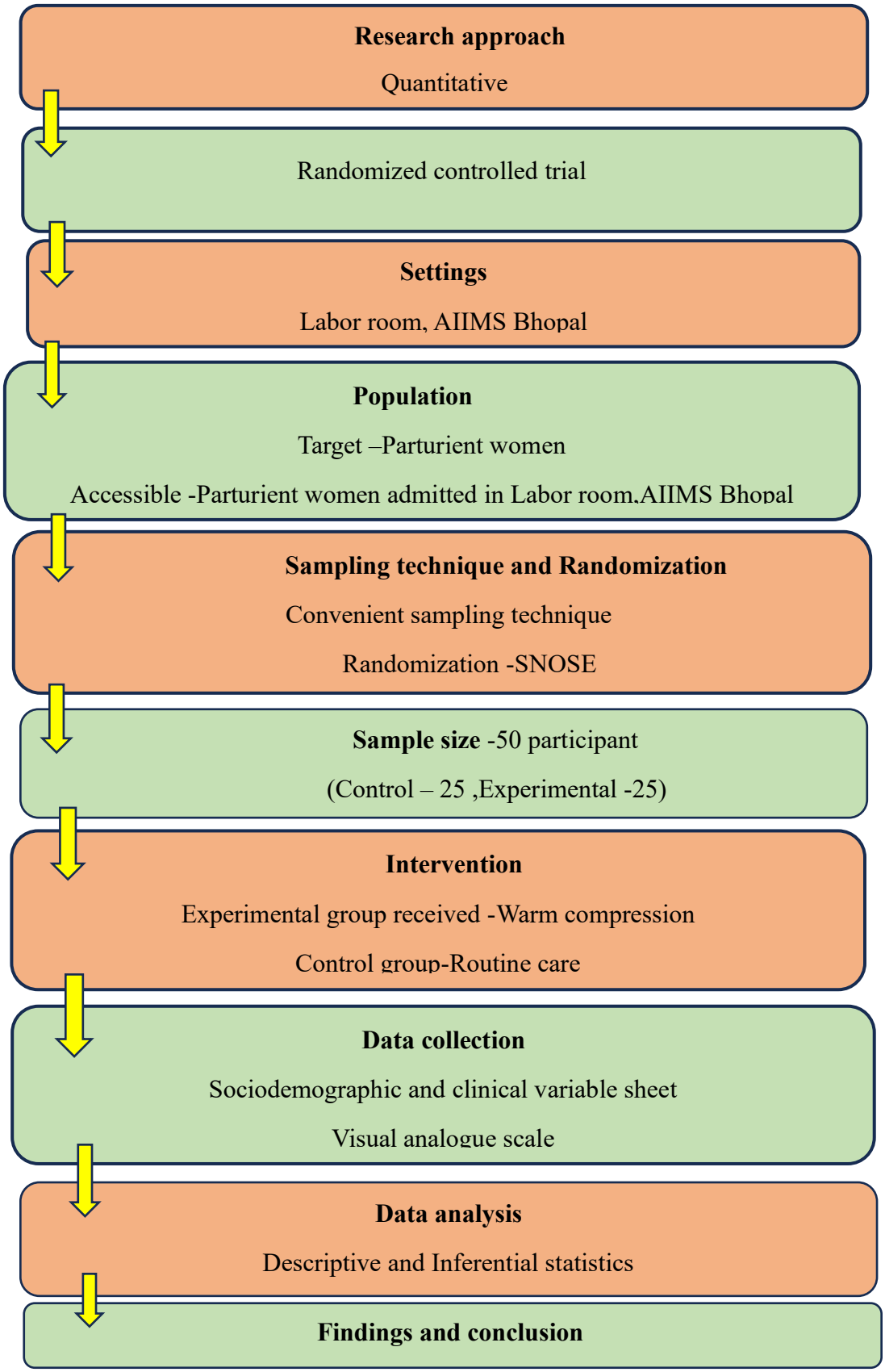

FIG 3: – Schematic representation of research methodology

Research Design

Research design can also be considered as a blueprint or the roadmap for the collection, measurement, and analysis of data[29].The research design refers to the overall strategy that one may choose to integrate the different components of the study in a coherent and logical way in order to ensure that research problem is effectively addressed.[28]

Randomized controlled trial.

In present study the researcher selected study design as **randomized controlled trial design** for the achieving the objectives and testing the hypothesis. In the experimental approach investigator determine the cause-and-effect relationship by applying intervention to the experimental group .it is considered one of the highest levels of evidence in clinical practice, due to their strong confidence and robustness in producing data. It provides straightforward investigation of cause–effect relationships with minimal bias and confounding factors.[29]

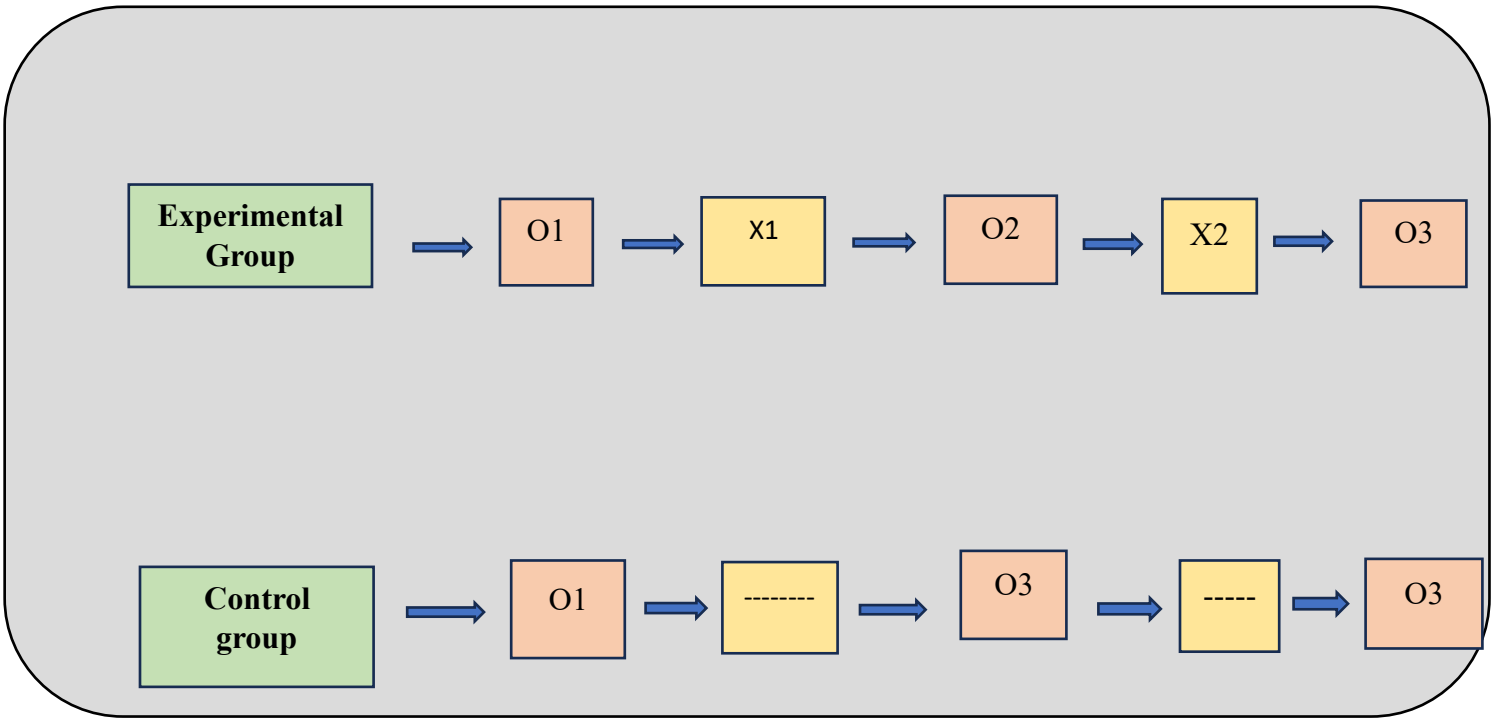

Fig 4: Symbolic representation of research design

The interpretation of the symbol is as follows:

O1: Pain intensity before warm compression of both groups

X1: 1st warm compression to the experimental groups

02: Immediate pain intensity after 1st warm compression of the both groups

X2:2nd warm compression to the experimental groups.

O3:Immediate Pain intensity after 2nd warm compression of the both groups

O4: Pain intensity after 30 minute of 2nd warm compression of the both groups.

------ : No treatment

Randomization :

Simple randomization with allocation ratio 1:1 was used for study. Randomization sequence was created by computer generated randomization list with the help of www.randomization.com . Allocation concealment was done to minimize the selection bias of the researcher. Allocation concealment mechanism adopted was Sequentially Numbered, Opaque Sealed envelopes(SNOSE).Each envelope contained the intervention to performed to the study participant which was unknown to the researcher. After enrolling the study participant, intervention assignment was ascertained by opening the sealed envelope.

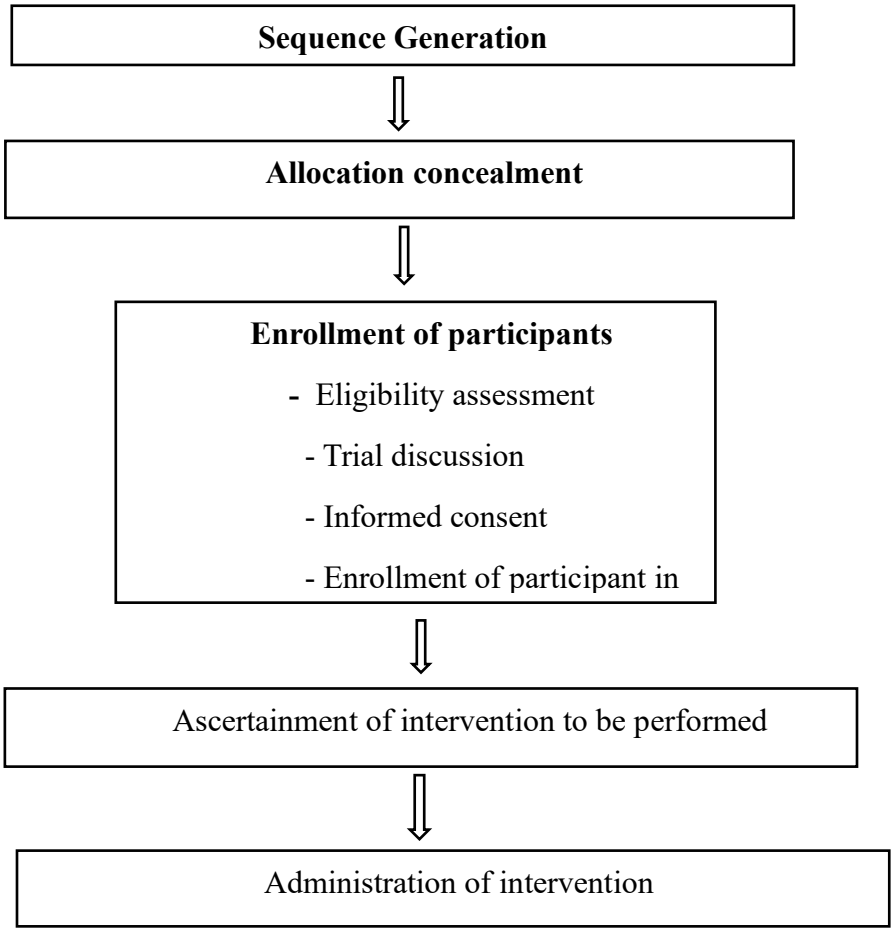

Fig 5 : Schematic presentation of the Randomization process

SNOSE Process :

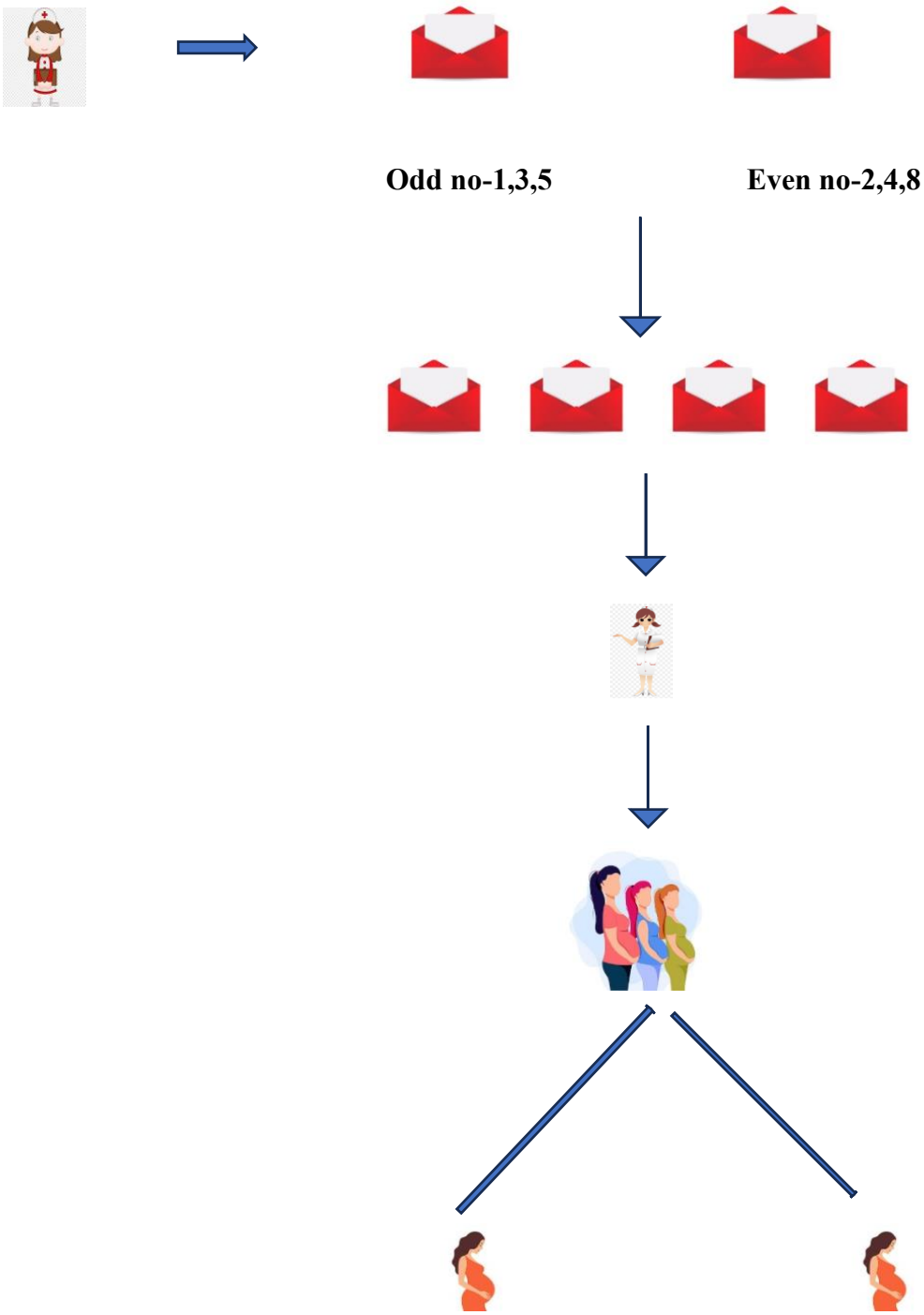

Fig 6 : figure showing the Sequentially Numbered, Opaque Sealed envelopes(SNOSE) Process

Variables under study :

Variables are characteristics or attribute of a person or object that can vary.[28]

Dependent and Independent variables

In this study, the dependent variable refers to intensity of labor pain and independent variable refers to warm compression.

Sociodemographic variables:

Sociodemographic variable assessed in this study included Age,Education,Ocuupation, Dietary pattern, BMI

Clinical variables:

Clinical variable assessed in this study included Gravida, antenatal Exercise, women receive any analgesic drug, abortion, Nature of onset of labor process, previous mode of delivery, previous medical condition.

Research Setting

The research setting can be the physical, social and cultural site where the researcher conducts the study.[49]

The study was conducted in the Labor room of AIIMS,Bhopal.It is 1100 bedded tertiary care hospital. The institute was unveiled on 26th January, 2013 for public service. The hospital is renowned fortis excellence in medical expertise ,Nursing care and quality diagnostic services. All facilities are provided for conducting normal, high risk and instrumental deliveries. Various department such as family planning, blood bank, dental

endocrinology, human milk bank neonatal intensive care units and oncology ward which are providing comprehensive care for entire Madhya Pradesh and for neighboring states.

Population

Population can be defined as a group of individual, items or objects from which samples are taken from measurement.[29]

The target population is the population into which the researcher would like to generalize his or her results. In this study, target population refers to A parturient women in first stage of labor.[28]

The accessible population is the aggregate of all cases that confirm to the designated criteria and that are accessible to the researcher as a pool of subjects for the study.[28] In the present study, Parturient women admitted in tertiary care hospital, Bhopal(AIIMS,Bhopal)

Sample -Sampling is the process in which take representative case from entire population.[50]Sample in the present study were parturient women during data collection period.

Sampling Criteria- Sampling criteria is the list of the characteristics essential for inclusion or exclusion in the target population.[28]

Sample inclusion criteria :

- Parturient women who were willing to participate in this study.
- Parturient women who were in active stage of labor.
- Parturient women with normal course of pregnancy

Sample exclusion criteria:

- Parturient women with visible bed sore in Lumbo-sacral region
- Parturient women who underwent spinal surgeries
- Parturient women who were diagnosed with hypotensive disorder

Sample size

A sample is a smaller group of subjects drawn from the population in which a given study was conducted for a purpose of drawing conclusions about the population targeted.

The formula for the sample is given in equation at the confidence interval of 95% with level of significance of 0.05 The formula adopted for sample size estimation in this study is:

The sample size was calculated based on previous review of literature it is conducted in India from this study taken standard deviation and mean the study was:

Kaur, Jasvir, Poonam Sheoran, Simarjeet Kaur, and Jyoti Sarin. "Effectiveness of Warm Compression on Lumbo-Sacral Region in Terms of Labour Pain Intensity and Labour Outcomes among Nulliparous: An Interventional Study." *Journal of Caring Sciences* 9, no. 1 (March 1, 2020): 9–12. https://doi.org/10.34172/jcs.2020.002 [42]

Formula for sample size calculation [51]

$$n \geq \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \, (\sigma_1^2 + \sigma_2^2 / r)}{(\mu_1 - \mu_2)^2}$$

Experimental group's mean and standard deviation =7.55 ± 0.87

Control group's mean and Standard deviation =7.68 ± 0.97

n = Sample size to be studied

Z 1-α/2 = 1.96 [at 5 % alpha]

Z 1-β = 0.84 [at 20% beta or 80%power]

σ = SD difference of outcome variable

Calculated sample size was = 42

Attrition rate for the present study is 10%

Researcher rounded of the sample size and added 10% attrition = 50 sample (25 in control ,25 in Experimental)

Sampling technique

Sampling technique is the process in which we take representative sample from population that could be studied for their topic so that they will be able to draw conclusion about the entire population.[28]There are different type of sampling technique such as simple random, purposive etc. in the present study sampling technique used was non-probability convenient sampling technique.

Convenient sampling technique is a specific type of non-probability sampling method that relies on data collection from population members who are conveniently available to participate in study.[51]

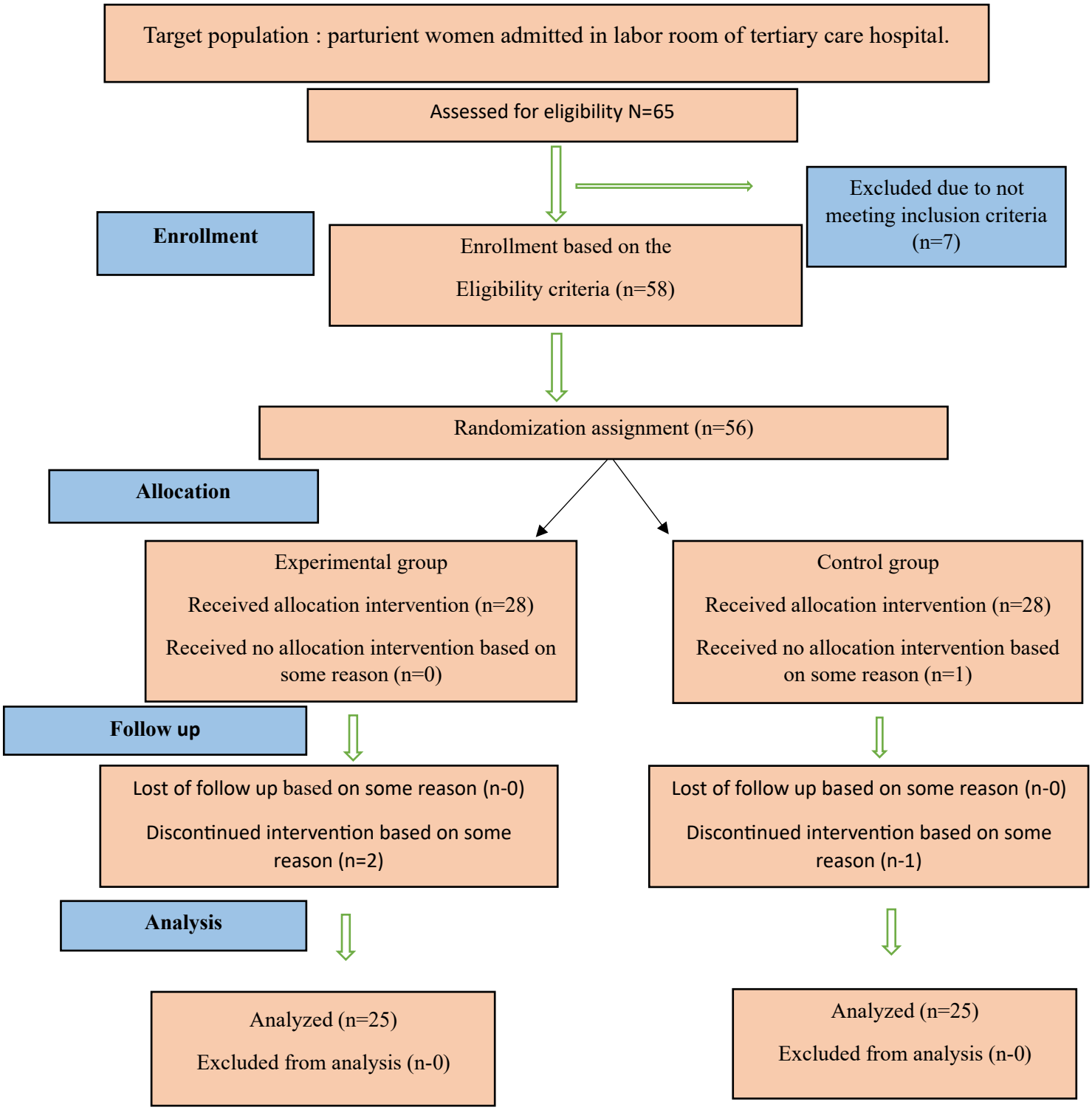
Target population : parturient women admitted in labor room of tertiary care hospital.
Assessed for eligibility N=65
Excluded due to not meeting inclusion criteria (n=7)
Enrollment
Enrollment based on the Eligibility criteria (n=58)
Randomization assignment (n=56)
Allocation
Experimental group
Received allocation intervention (n=28)
Received no allocation intervention based on some reason (n=0)
Control group
Received allocation intervention (n=28)
Received no allocation intervention based on some reason (n=1)
Follow up
Lost of follow up based on some reason (n-0)
Discontinued intervention based on some reason (n=2)
Lost of follow up based on some reason (n-0)
Discontinued intervention based on some reason (n-1)
Analysis
Analyzed (n=25)
Excluded from analysis (n-0)
Analyzed (n=25)
Excluded from analysis (n-0)

Figure 7; CONSORT Flow diagram of the study

Data Collection Tools

The most crucial aspect of any research is data collection, which actually provides information to research questions generated by the researcher in the study. Hence, data collection relies on the tool which is used for the study. The tool used in the present study consist of self-structured questionnaires on sociodemographic and clinical variables and standardized tool used in the study was visual analogue scale (VAS) for assessment of intensity of labor pain.

Development and Description of the tool:

Development of the tool- The investigator prepared the tool according to the objectives of the study, in the light of literature which were reviewed and relevancy to the clinical practice. The tool was developed in context of the parturient women who were in 1st stage of labor admitted in tertiary care hospital ,Bhopal

1. Extensive review of literature was done through books, national and international journals, published researches to find out information on parturient women with labor pain.
2. Preparation of first draft of the tool including necessary questions which may show association with the labor pain.
3. Personal consultation and discussion with obstetricians, nursing experts, naturopathy Practioner, Psychologist , Guide and Co-guide and suggestions were taken and made changes in the tool and find out the content validity index to make the questionnaire a valid tool.
4. Preparation of final draft of the questionnaire and finalized the content of the questionnaires.

Description of the tool-The research tool is divided into 2 sections where section I consist of two parts- Part A and Part B and section II.

SECTION I(A): Socio-Demographic Data

It is a self-structured questionnaire which includes 5 items such as Age, Education, Occupation , Dietary pattern, BMI

SECTION I(B): Clinical Profile

It is also a self-structured questionnaire includes 7 items such as Gravida, Antenatal Exercise, Women receive any analgesic drug, Abortion, Nature of onset of labor process, Previous mode of delivery, Previous medical condition.

SECTION II: Visual analogue scale

The visual analogue scale (VAS) is one of the standardized pain rating scales used for the first time in 1921 by Hayes and Patterson. It is often used in epidemiologic and clinical research to measure the intensity or frequency of various symptoms. Visual Analogue Scale(VAS) will be used to assess intensity of labor pain in parturient women.[52]

No pain-0-4 mm

Mild pain-5-44 mm

Moderate pain-45-74 mm

Severe pain-75-100 mm

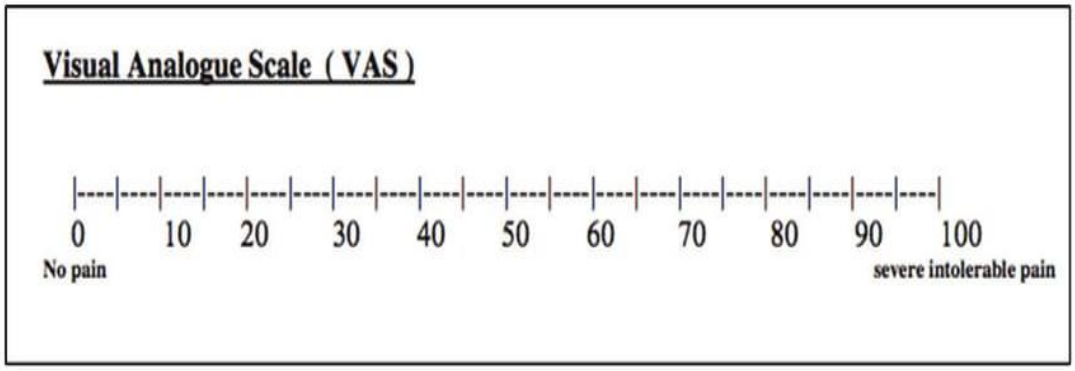

Table 1 : Tool sections

S.no	Section of the tool	Type of tool	Data collection technique
1	Socio demographic data	Self- structured	Paper pen method
2	Clinical profile	Self- structured	Paper pen method
3	Visual analogue scale	Standardized	Interview

Validity and Reliability of the Study

Validity- Validity always relates to the extent to which the research data as well as the methods for finding the data are accurate, honest and on target.[53]

Validity of Socio-Demographic Data & Clinical Profile –

The face validity of the tool was established after discussion with the guide and co guide whereas the content validity was established by scale content validity index where the self-structured tool (including Sociodemographic Questionnaire and Clinical Profile) was submitted to 15 experts (3 Obstetricians, 9 Nursing Experts and 1 Naturopathy doctor). Experts were requested to judge the tool for its clarity, relatedness, sequence, meaningfulness, and content. Suggestions were given by the 9 experts and modified. The tool which was developed in English was translated into Hindi.

Table 2: Scale Content validity Index values

S.no	CVI Value	Sociodemographic questionnaires	Clinical Profile
1.	S-CVI(Ave)	0.92	0.91

Reliability :

Reliability According to Sekaran and Bougie (2010), reliability of measurement is established by examining the stability and consistency of the data. [54]

The reliability was established by inter rater reliability. For the sociodemographic data (r=1) and Clinical profile (r=0.93).

Calibration certificate of lotion thermometer was obtained

Ethical consideration

Research ethics are the codes of behavior adopted by a group suggesting what member of a group thought to do under a given circumstance.[54]

All the ethical clearances were obtained prior to the commencement of data collection process are listed below

Ethical Clearance

Ethical clearance was obtained from the Institutional human ethics committee student research(IHEC-SR).

The registered LOP number was AIIMS /BPL/IHECSR/July/22/MscN/18 and the trial was registered under the clinical trial registry -INDIA (CTRI).the registration number for this trial was CTRI/2023/10/058413, Registered on 6/10/2023.

Administrative permission

The investigator took the permission from Medical Superintendent and Principal of Nursing College, AIIMS Bhopal and also notified to HODs and Nursing Officers of Obstetrics and Gynecology department prior to data collection.

Informed consent

The investigator provided the informed consent form and written participant information sheet was given regarding the details of the study and explained to all the parturient women before enrolment to the study. The involvement of benefits and harm (none) as well as whom to contact in case of doubt were explained to the study participants. The anonymity was maintained by assigning code numbers for identification not names as names were not used in the study. The confidentiality of the participant was maintained as the data was shared only with the guide and Co-guide.

Pilot Study

A Pilot study is a small preliminary investigation of the main study to evaluate feasibility, cost and to improve the study design before actual full-scale study. It is designated to

acquaint the investigator with the problems to be corrected in preparation for the larger study To assess the feasibility of conducting the main study and to obtain information for improving the project, a pilot study was conducted from the 6/10/2024 to 8 /10/ 2024.In this study 6 parturient women were include. The pilot study was conducted at AIIMS Bhopal, M.P to assess the feasibility of the study and 6 parturient women were taken. both groups had equally 3 participants conducted in labor room AIIMS,Bhopal were selected by convenient sampling method and randomization done with help of (SNOSE) .The subjects included in the pilot study were marked for exclusion in the main study. The collected data were analyzed using descriptive and inferential statistics and findings were found reliable and the researcher was able to measure the research variables according to study objectives.

Procedure of data collection

Data collection is the vital aspect of a research study where the tools of the study are used to collect the data from the participants. The investigator obtained permission from the concerned authorities to conduct the study in the recommended setup prior to the data collection process.it consist of following phase.

Phase I : **Pre assessment :**

The researcher introduce herself and established a good rapport with parturient women, The procedure was explained to the parturient women and after that obtained informed consent. The investigator assessed the intensity of labor pain in both group by using visual analogue scale.

Phase II: After assessing the intensity of labor pain applied warm compression at lumbo-sacral region for 20 minutes to the parturient women Who were in experimental group.

and provide routine care to the control group, immediately assess intensity of labor pain by using VAS in both groups. After that 30-minute interval again administer warm compression for 20 minutes to the experimental group and provide routine care to the control group ,immediately assess the intensity of labor pain in experimental and control group. after 30-minute interval assessed intensity of labor pain in both groups by VAS.

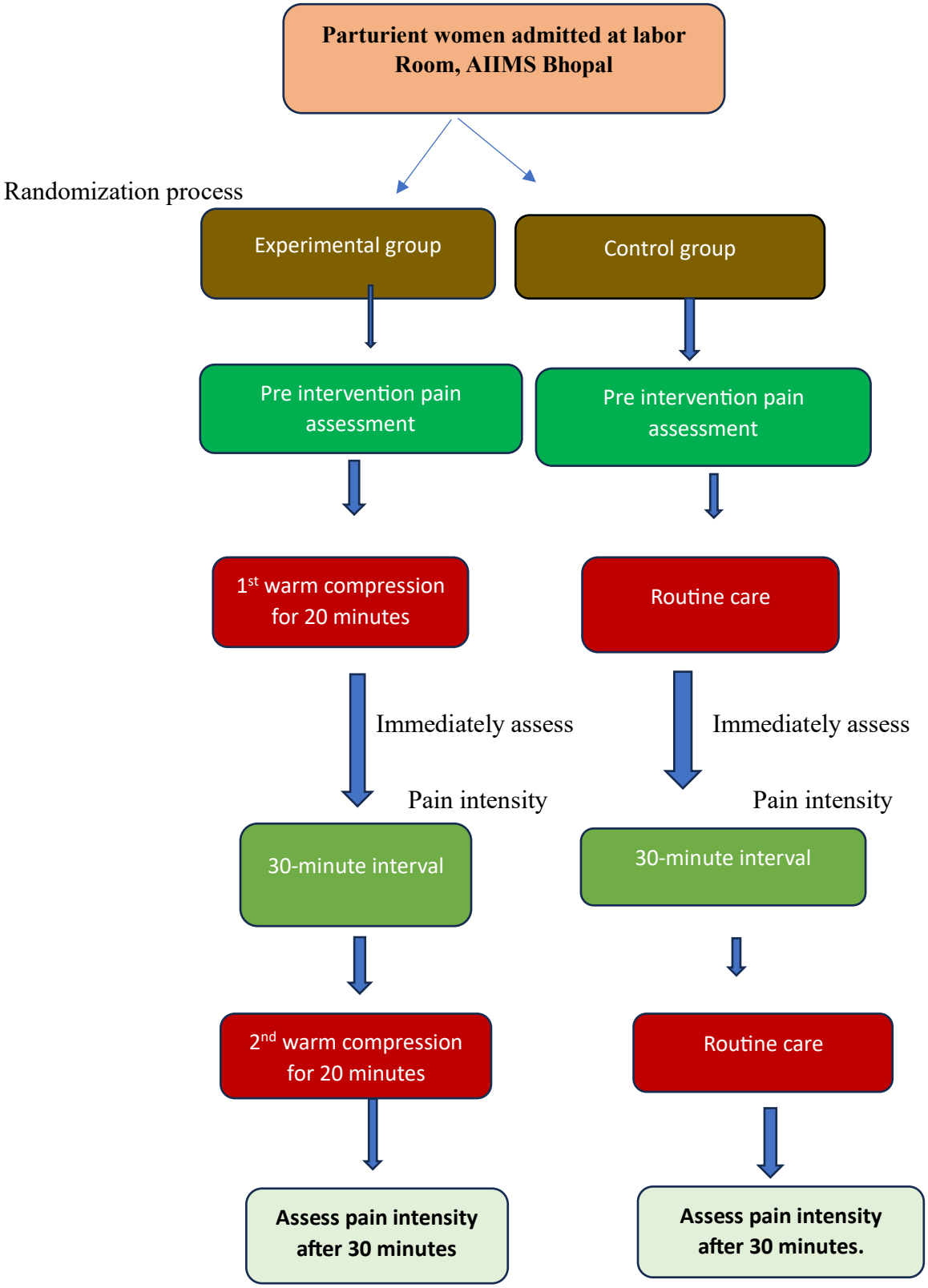

Fig 7 ; Flowchart showing the data collection procedure

Intervention protocol.

Place : Labor room, All India Institute of Medical Science, Bhopal.

Intervention : Warm compression at lumbo- sacral region.

Duration and time : Two-time warm compression for 20 minutes with 30-minute interval.

Administered by : Researcher only

Recipients : Parturient women in 1st stage of labor

Definition :

In this study, application of warm compression refers to using a clean cotton cloth of 15x15cm dimension and 1cm thick soaked in warm water with a temperature of 122-140°F (50-60°C) and applied and compressed on the lumbo-sacral region for 20 minutes in frequency of 2 time with 30-minute interval

Purpose :

- To increase blood flow at the lumbo-sacral region
- Helps to relieve labor pain

Equipment :

- ✓ clean cotton cloth (15cm length, 15cm width, 1 cm thickness)
- ✓ Mackintosh
- ✓ Draw sheet
- ✓ bucket
- ✓ lotion thermometer
- ✓ kidney tray
- ✓ Dry towel

Preliminaries :

- Explain the procedure to the women and take consent.
- Wash hands
- Maintain privacy
- Keep the mackintosh under parturient women's back.
- Give left lateral position

Intervention :

- Assess the pre interventional intensity of labor pain of parturient women by using visual analogue scale
- Fill the basin/bucket of half warm water then measure the temperature(50-60 degree Celsius.)by lotion thermometer
- Then soak the cloth 30 second and squeeze it.
- Apply warm compression at lumbo-sacral region for 20 minutes.
- Reapplying it after every 5 minutes and check the temperature of water in during the procedure and changing it as required.
- Then dry this area by dry towel and assess pain level by using visual analogue scale
- After 30 minutes again give second warm compression
- Assess intensity of the labor pain immediately and after 30 minutes.

After care :

- Give comfortable position to women
- Record and report
- Dispose the waste
- Wash all article.

Plan for data analysis

Data analysis is the systematic organization and synthesis of research data and testing of research hypothesis using those data. For the present study, the descriptive and inferential statistics were used to analyses the collective data on the basis of objectives of study. Data was collected, tabulated and presented in form of table, graphs and figures. Kolmogorov-Smirnov test and Shapiro Wilk test was used to check the normality of the data and independent t -test was performed to determine the effectiveness of warm compression at lumbo-sacral region in terms of intensity of labor pain.

Summary: This chapter dealt with the research methodology adopted for the study and included research approach, research design, setting, population, sample and sample size, sampling criteria, sampling technique, data collection techniques, ethical consideration, description of the tools, pilot study, the procedure for data collection and plan for data collection. The study adopted a quantitative approach with randomized controlled trial design. ethical clearance was obtained from the Institutional Ethical Committee and finally descriptive and inferential statistics were used for data analysis.

CHAPTER - 4

ANALYSIS AND INTERPRETATION

Data analysis is a systematic process that involves organizing and synthesizing data to address research questions and test hypotheses.[49]

The term analysis refers to the computation of certain resources along with searching for patterns of relations that exists among data groups. Analysis of data in a general way involves a number of closely related operations, which are performed with the purpose of summarizing the collected data, organizing them in such a manner that they answer the research questions.[50]

This chapter deals with analysis and interpretation of findings collected from parturient women who are in first stage of labor admitted in labor room using Self structure tool and Visual analogue scale(VAS) The collected data transformed into interpretable form so that it can answer the research question generated by the researcher.

The gathered data were analyzed using descriptive and inferential statistics according to the objectives and hypotheses of the study. The data collected by researcher underwent meticulous analysis utilizing MS Excel 365 and IBM SPSS statistics (version 22)

Organization of the findings

The present study findings are delineated into following headings:

Section I – Descriptions of sample characteristic.

Section 1.1 – Description of sociodemographic characteristic.

Section 1.2 – Description of Clinical characteristics.

Section II - Finding related to assessment of the Intensity of labor pain in Control group.

Section III- Finding related to assessment of the Intensity of labor pain in Experimental group.

Section IV - Effectiveness of warm compression at lumbo-sacral region on intensity of labor pain among parturient women.

Section V - Association between the intensity of pain with selected sociodemographic and clinical variable.

Section I

Descriptions of sample characteristic

The section deals with the description of selected sociodemographic and clinical variables of the sample(Parturient women) in terms of Frequency percentage and homogeneity

Section 1.1 :Descriptions of sociodemographic characteristics :

Frequency, percentage distribution and homogeneity of demographic variable among parturient women.

Table 3 **(N=50)**

Age	Control(N=25)		Experimental(N=25)		Fisher exact test	df	p-value
	Frequency	Percentage (%)	Frequency	Percentage (%)			
18-24	6	24.0%	9	36.0%	6.047	4	0.133
25-30	13	52.0%	11	44.0%			
Above 30	6	24.0%	5	20.0%			
Total	25	100.0%	25	100.0%			
Education							
Professional Degree	0	0	0	0	21.23	16	0.015
Graduate	13	52.0%	12	48.0%			
Diploma	3	12.0%	2	8.0%			
High School	5	20.0%	5	20.0%			
Middle School	2	8.0%	5	20.0%			
Primary School	2	8.0%	1	4.0%			
Illiterate	0	0	0	0			

Total	25	100.0%	25	100.0%			
Occupation							
Professional	1	4.0%	1	4.0%	13.998	9	1.0
Semi Professional	0	0	0	0			
Clerical/Shop/Farmer	1	4.0%	1	4.0%			
Skilled Workers	1	4.0%	1	4.0%			
Semi-Skilled Worker	0	0	0	0			
Unskilled Worker	0	0	0	0			
Unemployed	22	88.0%	22	88.0%			
Total	25	100.0%	25	100.0%			
Dietary							
Vegetarian	16	64.0%	17	68.0%	10.22	1	1.0
Non-vegetarian	9	36.0%	8	32.0%			
Total	25	100.0%	25	100.0%			
BMI							
Underweight <18.5	0	0.0%	2	8.0%	2.27	3	0.395
Normal 18.6-22.9	20	80.0%	14	56.0%			
Overweight 23-24.9	5	20.0%	6	24.0%			
Obese >25	0	0.0%	3	12.0%			
Total	25	100.0%	25	100.0%			

Interpretation : Data represented in table 3 depicted that Majority of parturient women belong from 25-30 age group in Control (52.0%)and Experimental group(44.0%).Majority of the 13 (52.0%) in experimental group and 12(48.0%) women were control group, 44 (88.0%) women were unemployed in both groups. Majority 64.0% of parturient women in the experimental group and 68.0 % of parturient women in the control group was vegetarian. Majority 80.0% of parturient women in control group and 56.0% in experimental group had normal BMI. In terms of the sociodemographic characteristics as the $p > 0.05$. therefore, both the groups were homogenous in nature as tested by Fisher exact test.

Section 1.2 :Descriptions of clinical characteristics :

Frequency, percentage distribution and homogeneity of clinical variable among parturient women.

Table 4 **(N=50)**

	Control(N=25)		Experimental (N=25)		Fisher exact	df	p-value
Gravida	**Frequency**	**Percentage (%)**	**Frequency**	**Percentage (%)**			
Primigravida	17	68.0%	16	64.0%	2.019	2	0.364
Multigravida	8	32.0%	9	36.0%			
Total	25	100.0%	25	100.0%			
Exercise							
Regular Walking	3	12.0%	5	20.0%	5.56	6	0.922
Breathing Exercise	1	4.0%	1	4.0%			
Pelvic Exercise	1	4.0%	0	0.0%			
No	20	80.0%	19	76.0%			
Total	25	100.0%	25	100.0%			
Analgesic							
Yes	5	20.0%	8	32.0%	2.492	2	0.310
No	20	80.0%	17	68.0%			
Total	25	100.0%	25	100.0%			
Abortion							
0	22	88.0%	23	92.0%	5.083	4	0.990
1	2	8.0%	1	4.0%			
>2	1	4.0%	1	4.0%			
Total	25	100.0%	25	100.0%			
Nature of onset labor process							

Induced	14	56.0%	12	48.0%	2.02	1	0.821
Spontaneous	11	44.0%	13	52.0%			
Total	25	100.0%	25	100.0%			
Previous mode of delivery?							
Normal Vaginal Delivery	5	20.0%	6	24.0%	2.067	1	0.349
Lower segment caesarean section	0	0	0	0			
Instrumental Delivery	0	0	0	0			
Not Applicable	20	80.0%	19	76.0%			
Total	25	100.0%	25	100.0%			
Does the women have any of the following medical condition?							
Rheumatoid Arthritis	0	0	0	0	Constant		
Kidney stone or infection	0	0.0%	1	4.0%			
Any spinal surgery	0	0	0	0			
Herniated disc	0	0	0	0			
No any medical condition	25	100.0%	24	96.0%			
Total	25	100.0%	25	100.0%			

Interpretation- Data represented in table 4 depicted that Majority of parturient women were primigravida in Experimental(68.0%) and control(64.0%) groups. Majority of the parturient women done not any previous exercise in control(80.0%) and experimental group(76.0%).20 (80.0%) women in experimental group and 17(68.0%) women in control group not received any analgesic drug. Majority 22(88.0%) of parturient women in Experimental group and 23 (92.0%) of parturient women in the control group had no history of abortion. Majority of the

14(56.0%)women had induced labor in control group 13 (52.0%) women had spontaneous labor in experimental group.5(20.0%) in control group 6(24.0%) in Experimental group had previous normal delivery. Majority of parturient women 49 (99.0%) had no any medical condition. In terms of the clinical characteristics as the $p > 0.05$. therefore, both the groups were homogenous in nature as tested by Fisher exact test.

Section II

Section II - Finding related to assessment the Intensity of labor pain in Control group.

Table 5

Frequency and percentage distribution of labor pain in control group.

Intensity of labor pain in control group (N=25)

PAIN LEVEL	PRE-TEST	POST TEST 1	POST TEST 2	POST TEST 3
	Frequency (%)	Frequency(%)	Frequency (%)	(Frequency)%
No pain(0-4mm)	0	0	0	0
Mild pain(5-44mm)	9(36.0%)	7(28.0%)	0(0%)	0(0.0%)
Moderate pain (45-74mm)	16 (64.0%)	18(72.0%)	19(76.0%)	10(40.0%)
Sever Pain(75 - 100mm)	0 (0.0%)	0(0%)	6(24.0%)	15(60.0%)
Total	25 (100.%)	25(100.0%)	25(100.0%)	25(100%)
Mean(mm) ± SD	48.01±12.08 **Moderate pain**	50.50±10.44 **Moderate pain**	63.60±10.94 **Moderate pain**	76.32± 45.64 **Sever Pain**

Interpretation – The table 5 data reveal an escalation in pain levels within the control group, evident in the pre-test, post-test 1, and post-test 2, majority of parturient women experienced moderate pain , while post-test 3 indicated that most women reported severe pain, this suggests a significant increase in pain among the parturient women.

Section III

Section III- Finding related to assessment of Intensity of pain in Experimental group.

Table 6

Frequency and percentage distribution of labor pain in Experimental group.

(N=25)

PAIN LEVEL	PRE TEST	POST TEST 1	POST TEST 2	POST TEST 3
	Frequency (%)	Frequency (%)	Frequency (%)	Frequency (%)
No pain(0-4mm)	0	0	0	0
Mild pain (5-44mm)	7(28.0%)	10(40.0%)	9(36.0%)	9(36.0%)
Moderate pain(45-74mm)	12(48.0%)	11(44.0%)	12(48.0%)	14(56.0%)
Sever Pain(75-100mm)	6(24.0%)	4(16.0%)	4(16.0%)	2(8.0%)
Total	25(100.%)	25(100.0%)	25(100.0%)	25(100%)
Mean (mm)± SD	56.80 ±20.25 **Moderate pain**	50.08%±19.21 **Moderate pain**	50.64±19.34 **Moderate pain**	45.64± 19.04 **Moderate pain**

Interpretation -Table 6 data shows that In posttest 1 Majority of the women had moderate pain in control group(72.0%) and experimental group(44.0%) , In post-test 2, Majority of women in the control group (76.0%) and the experimental group (48.0%) experienced moderate pain. In posttest 3 Majority of the women had severe pain in control group (60.0%)

and moderate pain in experimental group(56.0%).it indicated that after warm compression intensity of pain was reduced in Experimental group.

Section IV

Effectiveness of warm compression at lumbo-sacral region on intensity of labor pain among parturient women.

Data was normally distributed it was tested by K-S test so independent t test was performed.

Testing of hypothesis

To find out significance of mean difference in Intensity of labor pain scoring between experimental and control group, the following null hypothesis and alternate hypothesis was framed at 0.05 level of significance.

H0: There is no significant difference in intensity of labor pain among Experimental and control group at significance level 0.05 as measured by VAS scale.

H1 : There is significant difference in intensity of labor pain among Experimental and control group at significance level 0.05 as measured by VAS scale.

Table 7

Independent t test showing comparison of mean pain intensity score between two group (N=50)

Mean, Mean difference ,Standard deviation and "t" value of pretest and posttest labor pain scores of parturient women in experimental and control group.

Time points	Group	Mean ±SD	Standard Error Mean	t	df	P-value
Pre test	Control	48.01±12.08	2.10	1.86	24	0.068 (NS)
	Experimental	56.80 ±20.25	3.05			
Posttest1	Control	50.60 ±10.44	10.44	0.11	24	0.911 (NS)
	Experimental	50.08±19.21	19.21			
Posttest2	Control	63.60 ±10.94	2.16	2.75	24	0.011 (S)
	Experimental	50.64 ±19.34	3.80			
Posttest3	Control	76.32± 10.81	2.19	6.73	24	0.000 (S)
	Experimental	45.64 ±3.80	3.33			

(NS- Statically not significant),(S- Statistically significant)

Interpretation : Table shows that immediately after 2nd warm compression and after 30 minute of 2nd warm compression the intensity of labor pain in experimental group was significantly lower than control group respectively ($t_{(24)}= 2.75, p<0.05$; $t_{(24)}=6.73, p<0.05$) in posttest 2 and posttest 3 there are $p <0.05$ it indicates significant difference found between experimental and control group. This difference is not by chance Hence we reject the null hypothesis(HO) and accept the Research Hypothesis(H1).it is concluded that warm compression was effective in immediate and after 30 minute of 2nd warm compression.

Section -V

Association between the intensity of pain with selected sociodemographic and clinical variable.

To determine the association of intensity of pain among parturient women admitted in labor room AIIMS, Bhopal with selected socio-demographic and clinical variables was calculated using chi-square test and fisher exact test.

Table 8

Association of intensity of pain with selected sociodemographic and clinical variable.

(N=50)

S.no	Variable		f	Chi square test value	Fisher exact p value
Sociodemographic variable					
1.	Age	18-24 25-30 Above 30	15 24 11	0.86	0.65 (NS)
2.	Education (Kuppuswamy's scale)	Professional degree Graduate Diploma High school	0 25 5 10		0.80 * (NS)

		Middle school Primary school Illiterate	7 3		
3.	Occupation (Kuppuswamy's scale)	Professional Semi-professional Clerical/shop/farmer Skilled worker Semi -skilled worker Unskilled worker Unemployed	2 0 2 2 0 0 7		1.00* (NS)
4.	Dietary pattern	Vegetarian non- vegetarian	33 17	0.09	0.77 (NS)
5.	Body mass index (WHO guideline BMI ASIAN)	Underweight <18.5 Normal 18.6-22.9 Overweight 23-24.9 0bese >25	2 34 11 3		0.09* (NS)

Clinical variable					
6.	Gravida	Primigravida Multigravida	33 16		1.00* (NS)
7.	Did the women received any of the following exercise during antenatal period ?	Regular walking Breathing exercise Pelvic exercise No	8 2 1 39		0.85* (NS)
8.	Did women receive any analgesic drug	Yes No	13 37		0.35* (NS)
9.	Number of Abortion	0 1 ≥2	45 3 2	0.32	0.57 (NS)
10.	Nature of onset labor process	Induced Spontaneous	26 24	0.12	0.73 (NS)
11.	Does the women have any of the following	Rheumatoid Arthritis Kidney stone or infection	 1		-

	medical condition ?	Any spinal surgery Herniated disc No any medical condition	50		

(* = Fisher exact test) (f=frequency) (NS- Statistically not significant)

Interpretation – Table 7 shows that p> 0.05 in terms of association of pain intensity with selected sociodemographic and clinical variable. it indicates there were no significant association found between intensity of labor pain with selected sociodemographic and clinical variable

Summary

The chapter dealt with the presentation of analysis and interpretation of the data collected for the study. The analysis of data was presented in four sections. The first section depicted the distribution of sociodemographic and clinical variable in the population. The second section depicted the mean score of the experimental and control group before the intervention and after the intervention. The third section depicted the effectiveness of warm compression it is evaluated by using independent t test where no significant association found in posttest 2 and 3 it indicates warm compression was effective. Fourth section show significant association between intensity of pain and selected sociodemographic and clinical characteristic. There is no association found between intensity of pain with selected demographic and clinical variable

CHAPTER V

DISCUSSION

This chapter present the major findings of the present study and reviews them in relation to the findings from studies of other researchers, conclusion and implication in nursing, limitation and future recommendation of the research study.

The aim of the present study was assess the effectiveness of warm compression at lumbo-sacral region on intensity of labor pain during first stage of labor.

Major findings of the study -

Distribution of sociodemographic and clinical variable in population.

Majority of parturient women belong from 25-30 age and graduate. Majority of the women was unemployed in both groups. Majority 64.0% of parturient women in the experimental group and 68.0 % of parturient women in the control group was vegetarian. Majority 80.0% of parturient women in control group and 56.0% in experimental group had normal BMI.

Majority of parturient women was primigravida in both groups. Majority of the parturient women done not any previous exercise. Majority of the parturient women did not receive any analgesic drug. Majority 88.0% of parturient women in control group and 92.0% of parturient women in the control group had no history of abortion. Majority of the 56.0%women had induced labor in control group 52.0% women had spontaneous labor in experimental group. in control group and experimental group previous mode of delivery 20.0% and 24.0% respectively. Majority of parturient women in control group and experimental group had no any medical condition. Since no significant differences were

found, the groups were homogenous concerning demographic and clinical sheet at the time of recruitment to the study

Frequency and percentage of VAS Score in the Pretest ,Post test 1,Post test 2,Post test 3,Post test 4 in Both intervention and control group.

In the pre-test, the majority of the women had moderate pain in the control group (64.0%) and experimental group (48.0%).In posttest 1 Majority of the women had moderate pain in control group(72.0%) and experimental group(44.0%) , In post-test 2, Majority of women in the control group (76.0%) and the experimental group (48.0%) experienced moderate pain. In posttest 3 Majority of the women had severe pain in control group (60.0%) and moderate pain in experimental group(56.0%).

Effectiveness of warm compression at lumbo-sacral region

the intensity of labor pain in the intervention group was significantly less than control group in posttest 2($p<0.05$) and posttest 3($p<0.05$). So, there are significant difference found in pain intensity after 2nd warm compression Immediate, and after 30 minutes. The null hypothesis was rejected and alternative hypothesis was accepted.

Association of Intensity of pain with selected sociodemographic and clinical variable.

There is no association found between pain intensity and selected sociodemographic and clinical variable.

Discussion

The findings of the present study as per the research objectives are discussed and delineated under the following sections.

1. Sociodemographic and clinical characteristic of parturient women.
2. Intensity of labor pain in first stage of labor before warm compression in parturient women.
3. Intensity of labor pain in first stage of labor after warm compression in parturient women.
4. Effectiveness of warm compression at lumbo-sacral region among parturient women
5. Association between intensity of labor pain with selected demographic & clinical variable.

Sociodemographic and clinical characteristic in parturient women.

Majority of the women belong from 25-30 age group in both control group(52.0%) and experimental group(44.0%).The supported studies conducted in Northen region of India the study findings revealed that majority of the parturient women were belong from the 23–26-year age group.[42,44.]Another one supported study conducted in Blangkajeren of Indonesia in the year 2022 the study findings revealed that majority of the primigravida belong from 26-30 year age.[43]

In present study majority of the women were graduate in control(52.0%) and Experimental group(48.0%). A contradictory study conducted by Ritabala Devi in Pune, the findings indicated that the majority of women in both the control group (50.0%) and the experimental group (60.0%) had primary education.[44]

In present study parturient women had normal BMI .the supported study conducted in north Iran to investigate the effect of intermittent heat and cold on pain severity and childbirth outcomes. The study result revealed that the mostly women had Normal BMI in experimental (24.74±3.81)and control group(25.12±3.87).[55]

In the present study Majority of the women were unemployed in both groups, respectively control (80.0%), Experimental group (84.0%).A quasi-experimental study conducted to evaluate the effectiveness of heat therapy on lumbo-sacral region in terms of labor pain , the study revealed that the majority of women in both the control group (90.0%) and the experimental group (76.7%) were homemakers [44].Another supported study conducted in Iran to evaluate the effectiveness of heat therapy for pain and woman's satisfaction during physiological labor.the study findings revealed that majority of the women were homemaker in control(83.3%) and experimental group(96.7%).[56]

In present study, Majority 88.0% of parturient women in control group and 92.0% of parturient women in the Experimental group had no history of abortion, According to Kaur.et.al ,The majority of 86.4% women in the experimental group and 97.7% of the control group did not have any history of abortion [42] .In a study endorsed by Kacar Nukhet et al. (2020), the results indicated that the majority of women in both the experimental group (90.0%) and the control group (94.3%) had no history of abortion.[57]

Intensity of labor pain in first stage of labor before warm compression in parturient women.

In Pretest control group had 25 parturient women among them 9 parturient women had mild pain(36.0%) and 16 women had Moderate pain(64.0%),meanwhile In experimental group 7

parturient women had mild pain (28.0%), 12 parturient women had Moderate pain (48.0%),and 6 parturient women Sever pain (6.0%).

A similar study undertaken by Helti et al with aimed to assess the efficacy of warm compression in managing the intensity of labor pain. The study revealed that in the control group, 11 individuals (73.3%) experienced severe pain, and 4 individuals (26.7%) reported moderate pain. Conversely, in the treatment group for moderate pain, there were 12 participants (80.0%), 2 individuals with mild pain (13.3%), and 1 person with severe pain (6.7%).[43]

Peter Brownridge (1995) contends that labor pain is linked to uterine contractions, particularly in the first stage where the origin of the pain is visceral. The pain associated with uterine contractions triggers a widespread neuroendocrine stress response, leading to various physiological effects during the initial phase of labor. The intensity of the pain correlates with the strength of the contractions. Uterine ischemia is deemed less likely to contribute to the pain, as myometrial blood flow increases during uterine contraction.[58]

Intensity of the pain in experimental group in parturient women.

In Post test 1 Majority of the women had moderate pain in control group(72.0%) and experimental group(44.0%) , In Post-test 2, Majority of women in the control group (76.0%) and the experimental group (48.0%) experienced moderate pain. In Post test 3 Majority of the women had severe pain in control group (60.0%) and moderate pain in experimental group(56.0%).

In a quasi-experimental study carried out in 2022 to assess the effectiveness of warm compression in reducing the intensity of labor pain, the use of descriptive statistics revealed

significant findings. In the control group, 11 individuals (73.3%) reported experiencing severe pain, and 4 individuals (26.7%) reported moderate pain. Conversely, in the treatment group for moderate pain, there were 12 participants (80.0%), 2 individuals with mild pain (13.3%), and 1 person with severe pain (6.7%).[42]

According to Dian Puspita Yani's 2012 research on "The Effect of Giving Warm Water Compresses on Feeling Comfortable in the Active Phase I Labor Process," the Mann-Whitney U statistical test yielded a value of Z-2.049, which is less than the critical Z value from the table (Asymp sig: 0.04). This indicates a statistically significant effect of providing warm compresses in enhancing comfort during labor.[43]

Judging from the data above, it can be stated that after warm compresses were applied to the mother's back, lower abdomen, and perineum, the first stage of labor women who experienced labor pain experienced a significant decrease in pain levels. This is in accordance with the theory that warm compresses are a factor that affects the reduction of labor pain. Warm compresses can make the body feel relaxed because the warmth of the water helps dilate blood vessels so that blood flow is smooth. [10]

To alleviate the anxiety and pain during labor, warm compress therapy can be applied to expectant mothers. The application of heat widens blood vessels, promoting increased local blood flow, and effectively eases pain by eliminating inflammatory substances such as bradykinin, histamine, and prostaglandins that contribute to localized discomfort. Moreover, heat stimulates nerve fibers covering the pain gate, thereby hindering the transmission of pain signals to the spinal cord and brain. This process ultimately provides a comforting experience for mothers when she gave a birth.[18]

Effectiveness of warm compression at lumbo-sacral region among parturient women

Study result revealed that immediately after 2nd warm compression and after 30 minute of 2nd warm compression intensity of labor pain was significantly lower than control group respectively ($t=2.75, p<0.05; t=6.73, p<0.05$)

Our study findings are in line with the findings of a randomized controlled study conducted in district hospital Ambala, India, The study findings revealed that significant difference found between control and experimental group immediate after 1st,2nd and 3rd warm compression. Intensity of the labor pain score found lower in experimental group than control group respectively ($t=3.20; p<0.001$; $t=4.45; p<0.001; t=6.18; p<0.001$). [42] The similar findings noted in the quasi-experimental study Conducted in Indonesia on thirty primigravida women to Evaluate the effect of warm compression on the intensity of labor pain in primigravida Mother in the active phase. The study finding reveled that before warm compression pain level in primigravida were moderate pain (3.3%), severe pain (43.3%) and very severe pain (53.3%).and after warm compression mild pain (16.7%), moderate pain (33.3%), severe pain (26.7%), and very severe pain (23.3%) in primigravida women. there are significant decrease of pain level after warm compression.[43] The study conducted at Türkiye in 2021 on the effect of heat and massage therapy on lumbo-sacral region in terms of labor pain perception the study findings revealed that application of massage and hot pack reduced pain perception in active in transitional phase with 0.05 level of significance.[57] A supported study conducted in 2017 at Pune among sixty primigravida to evaluate the effectiveness of sacral warm compress on the level of pain during first stage of labor. Study finding revealed that in posttest 1, posttest 2 and posttest 3 there are significance difference found between experimental and control group at 0.05 level. It shows that warm compression was effective method to reduce

labor pain in primigravida mother. [44] A Randomized controlled trial conducted by Simin Taavoni with aimed of evaluate the effectiveness of heat therapy in terms of labor pain and women's satisfaction the study findings show that there was significantly difference found in experimental and control group ,mean pain score of experimental groups lower than control group and satisfaction score was higher in Experimental group than control group it indicated that heat therapy was effective to reduce labor pain in Active phase.[58] To evaluate the effectiveness of heat application on lumbo-suprapubic region in terms of labor pain a randomized trial conducted in Year 2017.it was conducted in Spain on 135 childbearing women. The study findings revealed that in pre intervention pain in experimental group(6.28 ±1.59 was higher than control group (5.57 ±1.87) after 30 minute of warm compression there are significantly decreased in experimental group(5.88± 1.82) and increased in control group (6.53 ±1.85). it shows that with application of warm compression pain level was decreased in experimental group.[48]A study was conducted in year 2023 to compare the effect of the infrared belt and hot water bag on the severity of labor pain. the result shows that the Mean score of pain was lower in Infrared belt group and hot water bag group compare to control group with significant level of 0.001 it indicated that hot water bag and infrared was effective to reduce labor pain.[59] There was no any contradictory study found

The results of above studied portray that the effectiveness of warm compression on the lumbosacral region in terms of labor pain relief has been studied and found to have positive outcomes. Warm compression involves the application of heat to the lower back area, specifically the lumbar and sacral regions, during labor. This method is often utilized as a non-pharmacological pain management technique. Conclude by all studied reported that warm compression can lead to increased blood flow, muscle relaxation, and a reduction in

muscle spasms. These effects contribute to a soothing and analgesic impact on the lumbar and sacral regions, which are commonly associated with pain during labor. The heat application may help in alleviating tension, promoting comfort, and potentially reducing the intensity of labor pain. It's important to note that individual responses to pain management techniques can vary, and the effectiveness of warm compression may depend on factors such as the woman's pain threshold, preferences, and the specific circumstances of labor. While warm compression can be a valuable addition to pain management strategies, it is often used in conjunction with other methods to provide comprehensive relief during the labor process.

Association between intensity of labor pain with selected demographic & clinical variable

In the Present study the significant association is not found between intensity of labor pain with sociodemographic variable.

Similar study conducted at Pune with aim of the evaluate the effect of sacral warm compression on the level of pain study finding revealed that There was no significant association found between the level of pain with selected sociodemographic variable[44].The study were conducted by Ms. Jayanthi in the year of 2011,The study findings revealed that there was no significant association found between the level of labor pain with their selected demographic variables.[61]

TS Chithra conducted Quantitative research, In the study result there was significant association found between pain perception with socio-demographic variable (age ,occupation)[62]

There was not too much study found regarding association of intensity of labor pain with selected sociodemographic and clinical variable.

Strength

It is randomized controlled trial it is considered one of the highest levels of evidence in clinical practice.

Use of the allocation concealment mechanism in random allocation for reduce the selection bias

Intervention and assessment was provided by researcher alone ensure equality in assessment and administration of intervention

Limitation

The parturient women who had less than 4 observations were excluded from the study.

Throughout the data collection phase, the researcher made extra efforts to obtain data included night shifts.

Implication for practice.

Nursing service

Warm compression should be made an integral part of pain relief in the management of labor pain.

Nurse can demonstrate the warm compression to birth companions for labor pain management it is easy and cost-effective.

Warm compression can be included in parenthood class as a pain relief management.

Nurse midwifery practitioners can incorporate this warm compression method into standard labor pain management for parturient women.

Nursing education

There could be increased emphasis on non-pharmacological pain management during labor in the nursing curriculum.

Nurse educator should encourage nursing student to utilize warm compression as measure for the labor pain reduction

An in-service education program should be implemented for nursing personnel, facilitating the acquisition of knowledge on reducing labor pain through the use of warm compress.

Nursing administration

Midwifery department should have policy decision to use warm compress as one of the essential nursing activities to reduce the labour pain.

Nursing administrator should organize in service education regarding warm compression in 1st stage of labor.

Nursing research

Nurse researcher can explore the more nursing intervention regarding labor pain management. Which are more convenient ,easily acceptable by parturient women and cost-effective.

Conclusion

The findings of the present study revealed that Warm compression is an easy and convenient method to decrease the pain intensity among parturient women in 1st stage of labor. It helps women to participate fully in the birthing process, to earn continuous caregiver support, to feel cared for and comforted, and have a more positive overall satisfied birthing experience. It is non-pharmacological pain management approach to reduce pain level among parturient women with no side effect. The non-pharmacological pain management approach can be explored further. There is no significant association between Intensity of labor pain with selected sociodemographic and clinical variables.

Recommendation

A further study is recommended at large scale sample with different setting

Comparative study can be done with other non-pharmacological labor pain management method.

Comparative study can be conducted between primigravida and multigravida women on effectiveness of warm compress during labor pain**.**

Summary

This chapter has discussed the findings of the study in relation to other studies. The studies conducted by other researcher also revealed similar and contradictory findings of the present study. This chapter also dealt with limitation of the study, Implication of the study, Conclusion of the study and recommendation for future studies.

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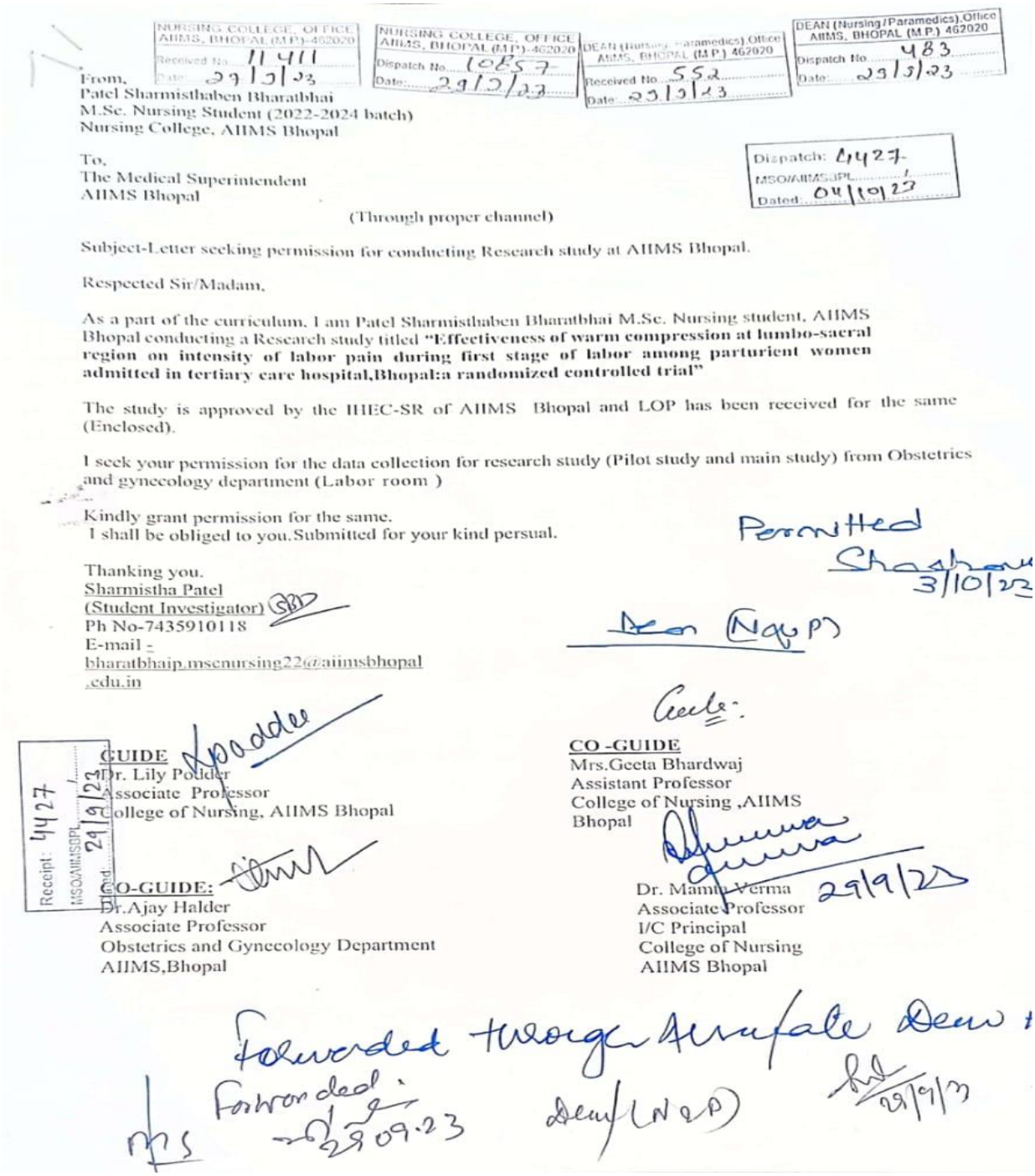
ANNEXURE 1

Letter seeking permission for the conducting study



NURSING COLLEGE, OFFICE AIIMS, BHOPAL (M.P)-462020 Received No. 11411 Date: 29/9/23

NURSING COLLEGE, OFFICE AIIMS, BHOPAL (M.P)-462020 Dispatch No. 10857 Date: 29/9/23

DEAN (Nursing/Paramedics) Office AIIMS, BHOPAL (M.P.) 462020 Received No. 552 Date: 29/9/23

DEAN (Nursing/Paramedics) Office AIIMS, BHOPAL (M.P.) 462020 Dispatch No. 483 Date: 29/9/23

From,
Patel Sharmisthaben Bharatbhai
M.Sc. Nursing Student (2022-2024 batch)
Nursing College, AIIMS Bhopal

Dispatch: 4427
MSO/AIIMS/BPL
Dated: 04/10/23

To,
The Medical Superintendent
AIIMS Bhopal

(Through proper channel)

Subject-Letter seeking permission for conducting Research study at AIIMS Bhopal.

Respected Sir/Madam,

As a part of the curriculum, I am Patel Sharmisthaben Bharatbhai M.Sc. Nursing student, AIIMS Bhopal conducting a Research study titled **"Effectiveness of warm compression at lumbo-sacral region on intensity of labor pain during first stage of labor among parturient women admitted in tertiary care hospital,Bhopal:a randomized controlled trial"**

The study is approved by the IHEC-SR of AIIMS Bhopal and LOP has been received for the same (Enclosed).

I seek your permission for the data collection for research study (Pilot study and main study) from Obstetrics and gynecology department (Labor room)

Kindly grant permission for the same.
I shall be obliged to you.Submitted for your kind persual.

Permitted
3/10/23

Dean (Nurs P)

Thanking you.
Sharmistha Patel
(Student Investigator)
Ph No-7435910118
E-mail -
bharatbhaip.msenursing22@aiimsbhopal.edu.in

Receipt: 4427 MSO/AIIMS/BPL 29/9/23

GUIDE
Dr. Lily Podder
Associate Professor
College of Nursing, AIIMS Bhopal

CO-GUIDE:
Dr.Ajay Halder
Associate Professor
Obstetrics and Gynecology Department
AIIMS,Bhopal

CO -GUIDE
Mrs.Geeta Bhardwaj
Assistant Professor
College of Nursing ,AIIMS
Bhopal

Dr. Mamta Verma
Associate Professor
I/C Principal
College of Nursing
AIIMS Bhopal
29/9/23

Forwarded through Almufale Dean
Forwarded
29.09.23
Dean (N&P)
29/9/23

ANNEXURE 2

Screening tool

1.Date of admission

2. Time of Admission

3.Are you able to understand Hindi or English [yes /No

---

4. Gravida

5.Gestational week based LMP/ abdominal palpation and USG findings

---

6.Any comorbidity ?

---

7. Any complication during antenatal period ?

---

8. Are you willing to participate in the study ?

SELECTED FOR THE STUDY –[YES/NO]

1.CODE NO----------

2.PLACE OF SCREENING----------

ANNEXURE 3

Part A- Tool for sociodemographic data collection

Instructions: Kindly tick and fill in the blanks with the most appropriate answer for each item. The information provided by you will be kept confidential and only be used for research purpose.

1. Participate Code number - ……
2. Age-……
3. Education (Kuppuswamy's scale)
   (a) Professional degree
   (b) Graduate
   (c) Diploma
   (d) High school
   (e) Middle school
   (f) Primary school
   (g) Illiterate
4. Occupation (Kuppuswamy's scale)
   (a) Professional
   (b) Semi-professional
   (c) Clerical/shop/farmer
   (d) Skilled worker
   (e) Semi -skilled worker
   (f) Unskilled worker
   (g) Unemployed
5. Dietary pattern
   (a) Vegetarian
   (b) non- vegetarian
6. Body mass index (WHO guideline BMI ASIAN)

   (a) Underweight <18.5

   (b) Normal 18.6-22.9

   (c) Overweight 23-24.9
   (d) 0bese >25

Part 2- Clinical sheet for collecting clinical variable

Instructions: Kindly tick and fill in the blanks with the most appropriate answer for each item. The information provided by you will be kept confidential and only be used for research purpose.

1. Gravida
   (a) Primigravida
   (b) Multigravida
2. Did the women received any of the following exercise during antenatal period ?
   (a) Regular walking
   (b) Breathing exercise
   (c) Pelvic exercise
   (d) No
3. Did women receive any analgesic drug
   (a) Yes
   (b) No
4. Number of Abortion
   (a) 0
   (b) 1
   (c) ≥2
5. Nature of onset labor process
   (a) Induced
   (b) Spontaneous

6. Previous mode of delivery ?

   (a) Normal vaginal delivery

   (b) Lower segment Cesarean section

   (c) Instrumental delivery

7.Does the women have any of the following medical condition ?

   (a) Rheumatoid Arthritis

   (b) Kidney stone or infection

   (c)Any spinal surgery

   (d)Herniated disc

   (e) No any medical condition

ANNEXURE -4

डेटा संग्रह के लिए उपकरण

सामाजिक जनसंख्याकिय डेटा

1. **भागीदार का पहचान नंबर**
2. **आयु**
   a) 18से कम
   b) 20-30
   c) 30 से ज्यादा
3. शिक्षा
   a) स्नातक
   b) डिप्लोम
   c) माध्यमिक शिक्षा
   d) पूर्व माध्यमिक शिक्षा
   e) निरक्सर
4. व्यवसाय
   a) वृतिक
   b) अर्धावृतिक
   c) क्लर्क
   d) कुशल कारीगर
   e) अर्धकुशल कारीगर
   f) बेरोजगार
5. आहार
   a) शाकाहारी
   b) माशाहारी
6. शरीर द्रव्यमान सूचनांक
   a) <18.4
   b) 18.4-24.9
   c) 25-30
   d) 30-34

नैदानिक डेटा

7. गर्भ रहना
    a) पहली बार गर्भवती
    b) एक बार से ज्यादा
8. पहले महिलाएं वव्यायाम का प्रसिशिकन लिया है
    a) चलना
    b) श्वास का व्यायाम
    c) पेल्विक व्यायाम
9. गर्भपात की संख्या
    a) 0
    b) 1
    c) 2
10. प्रस्वपीड़ा की शरुआत होने का स्वभाव
    a) प्राकृतिक
    b) प्रेरित
11. महिला ने कोई दर्द कम करने की दवाई ली थी ?
    a) हा
    b) ना
12. पहले प्रसूति कैसे हुए थी
    a) सामान्य योनि प्रसव
    b) निचला खंड सीजरन सेक्शन
    c) शस्त्र का उपयोग कर के प्रसूति
13. पहले महिला को कोई बीमारी थी
    a) धमनी का सूजन
    b) गुदे की पथरी
    c) रीढ़ की हड्डी की सर्जरी
    d) हेर्निएटेड डिस्क

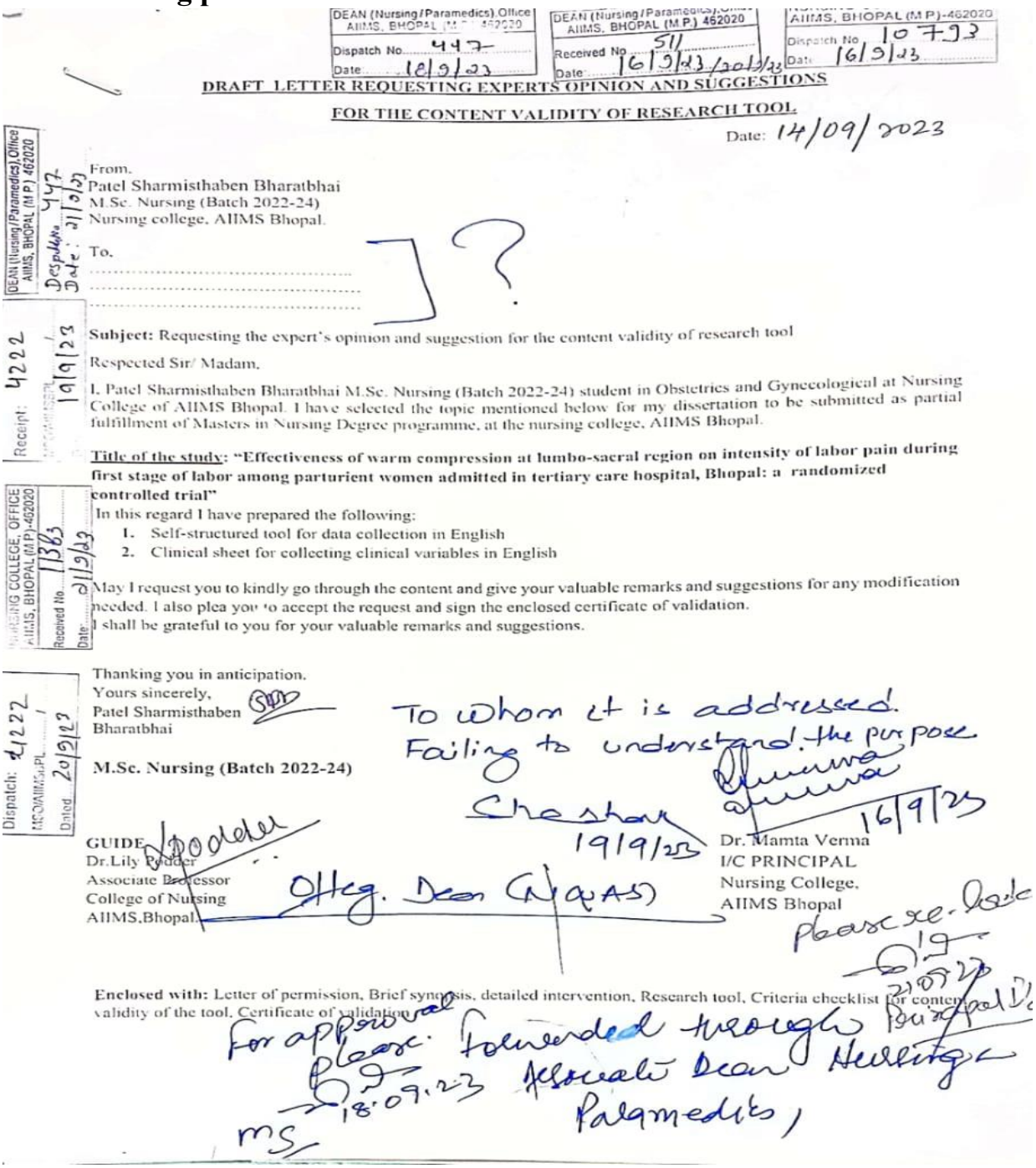
ANNEXURE 5

List of experts

S.No.	NAME OF EXPERTS	INSTITUTION	DESIGNATION
1.	Ms.Naseema Shafqat	AIIMS Bhopal	Assistant Professor
2.	Dr. Jyotinath Modi	AIIMS,Bhopal	Associate Professor
3.	Mrs. Anju Verma	CON, SGPGIMS	Associate Professor
4.	Dr. Arun K. Dora	AIIMS Bhopal	Associate Professor
5.	Dr. Seema Rani Chopra	GCON, Surat	Nursing tutor
6.	Dr. Prasuna Jelly	AIIMS, RISHIKESH	Associate Professor
7.	Mr. Himanshu Vyas	AIIMS, Jodhpur	Associate Professor
8.	Dharitri Swain	AIIMS,Bhubaneswar	Assistant professor
9.	Mrs. Niza Subramaniyam	CON, BHU	Assistant professor
10.	Mrs. Anitha Moncy	CON, BHU	Assistant Professor
11.	Dr. Shweta Patel	AIIMS,Bhopal	Assistant professor
12.	Dr.Bharti Singh	AIIMS,Bhopal	Assistant Professor
13.	Mrs. Vahitha arun	AIIMS,Raipur	Assistant professor
14.	Mrs.Koteshwari	AIIMS,Patna	Assistant professor
15.	Mrs. Manita Dalal	AIIMS Delhi	Nursing tutor
16.	Mrs. Sumathi	AIIMS Delhi	Nursing tutor
17.	Mrs.Sunita	AIIMS,Bhopal	Assistant nursing superintendent
18.	Mrs.Nivedeta	AIIMS,Bhopal	Assistant nursing superintendent

ANNEXURE 6

Letter seeking permission for tool validation



DEAN (Nursing/Paramedics) Office AIIMS, BHOPAL (M.P.) 462020
Dispatch No. 447 Date 16/9/23

DEAN (Nursing/Paramedics) AIIMS, BHOPAL (M.P.) 462020
Received No. 511 Date 16/9/23

AIIMS, BHOPAL (M.P.)-462020
Dispatch No. 10793 Date 16/9/23

DRAFT LETTER REQUESTING EXPERTS OPINION AND SUGGESTIONS

FOR THE CONTENT VALIDITY OF RESEARCH TOOL

Date: 14/09/2023

DEAN (Nursing/Paramedics) Office AIIMS, BHOPAL (M.P.) 462020 Despatch No. 447 Date: 21/9/23

Receipt: 4222 16/9/23

NURSING COLLEGE, OFFICE AIIMS, BHOPAL (M.P.)-462020 Received No. 1383 Date 21/9/23

From,
Patel Sharmisthaben Bharatbhai
M.Sc. Nursing (Batch 2022-24)
Nursing college, AIIMS Bhopal.

To,
.....
.....
.....

Subject: Requesting the expert's opinion and suggestion for the content validity of research tool

Respected Sir/ Madam,

I, Patel Sharmisthaben Bharatbhai M.Sc. Nursing (Batch 2022-24) student in Obstetrics and Gynecological at Nursing College of AIIMS Bhopal. I have selected the topic mentioned below for my dissertation to be submitted as partial fulfillment of Masters in Nursing Degree programme, at the nursing college, AIIMS Bhopal.

Title of the study: "Effectiveness of warm compression at lumbo-sacral region on intensity of labor pain during first stage of labor among parturient women admitted in tertiary care hospital, Bhopal: a randomized controlled trial"

In this regard I have prepared the following:

1. Self-structured tool for data collection in English
2. Clinical sheet for collecting clinical variables in English

May I request you to kindly go through the content and give your valuable remarks and suggestions for any modification needed. I also plea you to accept the request and sign the enclosed certificate of validation.
I shall be grateful to you for your valuable remarks and suggestions.

Dispatch: 4222 NSG/AIIMS/BPL Dated 20/9/23

Thanking you in anticipation.
Yours sincerely,
Patel Sharmisthaben Bharatbhai

M.Sc. Nursing (Batch 2022-24)

To whom it is addressed.
Failing to understand the purpose
Dhumma
Dhumma
16/9/23

Chethan
19/9/23

GUIDE
Dr.Lily Podder
Associate Professor
College of Nursing
AIIMS,Bhopal

Dr. Mamta Verma
I/C PRINCIPAL
Nursing College,
AIIMS Bhopal

Offg. Dean (A)(QAS)

Please see. Date 19-9-23
20/9/23
Principal I/C

Enclosed with: Letter of permission, Brief synopsis, detailed intervention, Research tool, Criteria checklist for content validity of the tool, Certificate of validation.

For approval please. Forwarded through Addl. Dean Nursing (Paramedics), 18.09.23
MS

ANNEXURE 7

Evaluation Criteria For Validation Of Tool

Socio-Demographic variable and clinical variable

Items	Highly relevant (5)	Quiet relevant (4)	Somewhat relevant (3)	Not relevant (2)	remarks

Suggestions-

ANNEXURE 8

Certificate of validation

This is to certify that the tool prepared by Patel Sharmisthaben Bharatbhai , M.Sc. Nursing 2022 batch student, Nursing college, AIIMS Bhopal, to be used in her study titled **Effectiveness of warm compression at lumbo-sacral region on intensity of labor pain during first stage of labor among parturient women admitted in tertiary care hospital, Bhopal: a randomized controlled trial"** has been validated by me and is found to be **valid/ not valid.**

Overall Remark-

Signature:

Name of the expert:

Designation:

Name of the Institution:

Official seal:

Date:

Place:

ANNEXURE 9

Translation certificate

CERTIFICATE OF TRANSLATION

TO WHOM IT MAY CONCERN

This is to certify that Ms. Patel Sharmisthaben Bharatbhai M.Sc Obstetrics and Gynecology Nursing student of Nursing College, AIIMS Bhopal is conducting research on topic "Effectiveness of warm compression at lumbo-sacral region on intensity of labor pain during first stage of labor among parturient women admitted in tertiary care hospital,Bhopal :a randomised controlled trial The Hindi version of research tool for this study is a true and accurate translation of the English version and is valid to collect data for research.

The Secondary School Dist. Dahod Chhapariya Ta Singvad

Seal & Signature : ..... Name Gari Jashvant bhai R.

of the language expert : Gari Jashvantbhai Ranchhodbhai

Designation : A.T. Teacher

Qualification : M.A. B.ed.

Date : 30-09-2023

Place : chhapariyad.

Scanned with ACE Scanner

ANNEXURE 10

Participate information sheet (English)

Title of the study: "A study to assess the effectiveness of warm compression at lumbo-sacral region on intensity of labor pain during first stage of labor among parturient women admitted in tertiary care hospital , Bhopal : a randomized controlled trial

Principal Investigators :
Ms. Sharmistha Patel
M.Sc obstetrics and gynecology nursing
AIIMS Bhopal
Guide
Dr. Lily podder
Associate professor,
Nursing college, AIIMS Bhopal
Co- guide
Mrs. Geeta Bhardwaj
Assistant professor,
AIIMS Bhopal
Co-Guide
Dr. Ajay Halder
Associate professor,
Obstetrics and Gynecology department
Funding : Self-funded

Introduction and Purpose of the study : I am conducting study on assess the effectiveness of warm compression at lumbo- sacral region on intensity of labor pain during first stage of labor among parturient women .labor is mostly unbearable pain for women it is most difficult part of pregnancy. during labor some women demanding cesarean section because of she cannot tolerate labor pain so it lead to increase rate of cesarean section. There are many pharmacological and non- pharmacological method for relieving in labor pain. Mostly women are prefer non- pharmacological method because this method have less side effect comparing to pharmacological method. In non- pharmacological various method are available investigator choose warm compression method. Hence, this study is aimed to assess the effectiveness of warm compression at lumbo- sacral region on intensity of labor pain during first stage of labor among parturient women admitted in tertiary care Hospital, Bhopal.

Participation – what is included?

a) Should I participate?

Participation in this research is completely voluntary.

b) What is expected of me if I join?
After obtaining informed consent, you will be asked your personal demographic data, Questionnaire to assess burden, social support, and family wellbeing. You provide the relevant details asked and cooperate the investigator.

c) How long will my participation in the study last?
The duration of the participation may last for 45 minutes by the investigator.

d) Do I have to come separately for this study or will additional tests be necessary?
No.

e) What are the potential benefits of joining?
There is no financial benefit involved in the study.

f) Potential loss and risk from participating in it ?
There is no harm or risk due to participation in this study. Non- pharmacological method includ warm compression it is easy, safe method . in which investigator will be use warm sponge it apply at lumbo-sacral region it causes vasodilation and worked bases on gate control theory of pain . it is not risky for women and child

g) What will happen to the information collected about me? All information collected will be kept strictly confidential. Access to data will be provided only to individuals permitted by law if deemed necessary

h) What happens if I change my mind about participating in this study?
You have the right to change your views at any time during the course of study without any damages or penalties

Whom should I contact for more information regarding this or if I have any question/doubts in my mind later?

If you want any information, you can contact

Dr. Shashank puwar
Member Secretary, Institution Human Ethics Committee.
Contact details: phone - 7773010099 and
email -ihecpgr@aiimsbhopal.edu.in

Dr. Mamta Verma,
Principal Nursing College, AIIMS Bhopal.
Contact details: phone- +919981540519,
Email- principal.nursing@aiimsbhopal.edu.i

ANNEXURE 11

Participate information sheet (Hindi)

<u>प्रतिभागी सूचना पत्र</u>

1. अध्ययन का शीर्षक: "तृतीयक देखभाल अस्पताल, भोपाल में भर्ती प्रसव कराने वाली महिलाओं के बीच श्रम के पहले चरण के दौरान प्रसव पीड़ा की तीव्रता पर लम्बो-सैकरल क्षेत्र में गर्म संपीड़न की प्रभावशीलता का आकलन करने के लिए एक अध्ययन: एक यादृच्छिक नियंत्रित परीक्षण

प्रधान अन्वेषक:

सुश्री शर्मिष्ठा पटेल

M.Sc प्रसूति एवं स्त्री रोग नर्सिंग

एम्स भोपाल

मार्गदर्शक

डॉ लिली पोडर

सह - प्राध्यापक,

नर्सिंग कॉलेज, एम्स भोपाल

सह-मार्गदर्शक

श्रीमती गीता भारद्वाज

सहेयक प्रोफेसर,

एम्स भोपाल

सह मार्गदर्शक

डॉ. अजय हलदर

सह - प्राध्यापक,

प्रसूति एवं स्त्री रोग विभाग

वित्तपोषक: स्व-वित्तपोषित

अध्ययन का परिचय और उद्देश्य: मैं प्रसव कराने वाली महिलाओं में प्रसव के पहले चरण के दौरान प्रसव पीड़ा की तीव्रता पर लम्बोसैक्रल क्षेत्र में गर्म संपीड़न की प्रभावशीलता का आकलन करने के लिए अध्ययन कर रही हूं। प्रसव ज्यादातर महिलाओं के लिए असहनीय दर्द है, यह इसका सबसे कठिन हिस्सा है। प्रसव के दौरान कुछ महिलाएं सिजेरियन सेक्शन की मांग करती हैं क्योंकि वह प्रसवपीड़ा बर्दाश्त नहीं कर पाती हैं इसलिए इससे सिजेरियन सेक्शन की दर बढ़ जाती है। प्रसव पीड़ा से राहत पाने के लिए कई औषधीय और गैर-औषधीय तरीके हैं। ज्यादातर महिलाएं गैर-औषधीय पद्धति को पसंद करती हैं क्योंकि औषधीय पद्धति की तुलना में इस पद्धति का दुष्प्रभाव कम होता है। गैर-औषध विज्ञान में विभिन्न विधियाँ उपलब्ध हैं अन्वेषक गर्म संपीड़न विधि का चयन करते हैं। इसलिए, इस अध्ययन का उद्देश्य तृतीयक देखभाल अस्पताल, भोपाल में भर्ती प्रसव कराने वाली महिलाओं के बीच श्रम के पहले चरण के दौरान प्रसव पीड़ा की तीव्रता पर लम्बोसैक्रल क्षेत्र में गर्म संपीड़न की प्रभावशीलता का आकलन करना है।

भागीदारी - क्या शामिल है?

ए) क्या मुझे भाग लेना चाहिए?

इस शोध में भागीदारी पूरी तरह से स्वैच्छिक है

ख) यदि मैं शामिल होता हूं तो मुझसे क्या अपेक्षा की जाती है?

सूचित सहमति प्राप्त करने के बाद, आपसे आपका व्यक्तिगत जनसांख्यिकीय डेटा, बोझ का आकलन करने के लिए प्रश्नावली, सामाजिक समर्थन और परिवार की भलाई के लिए कहा जाएगा। आप पूछे गए प्रासंगिक विवरण प्रदान करते हैं और आमंत्रित को सहयोग करते हैं

ग) अध्ययन में मेरी भागीदारी कितने समय तक चलेगी?

अन्वेषक द्वारा भागीदारी की अवधि 80 मिनट तक हो सकती है।

घ) क्या मुझे इस अध्ययन के लिए अलग से आना होगा या अतिरिक्त परीक्षण आवश्यक होंगे?

नहीं।

ई) शामिल होने के संभावित लाभ क्या हैं?

अध्ययन में कोई वित्तीय लाभ शामिल नहीं है।

च) इसमें भाग लेने से संभावित नुकसान और जोखिम?

इस अध्ययन में भाग लेने से कोई नुकसान या जोखिम नहीं है। गैर-औषधीय विधि में गर्म संपीड़न शामिल है यह आसान, सुरक्षित तरीका है। जिसमें अन्वेषक गर्म स्पंज का उपयोग करेगा, इसे कटि- त्रिक क्षेत्र में लगाया जाता है, यह वासोडिलेशन का कारण बनता है और दर्द के गेट नियंत्रण सिद्धांत पर काम करता है। यह महिलाओं और बच्चों के लिए जोखिम भरा नहीं है

छ) मेरे बारे में एकत्र की गई जानकारी का क्या होगा?एकत्र की गई सभी सूचनाओं को गोपनीय रखा जाएगा। यदि आवश्यक समझा जाए तो केवल कानून द्वारा अनुमत व्यक्तियों को ही डेटा तक पहुंच प्रदान की जाएगी

ज) यदि मैं इस अध्ययन में भाग लेने के बारे में अपना विचार बदल दूं तो क्या होगा?

आपको अध्ययन के दौरान किसी भी समय बिना किसी नुकसान या दंड के अपने विचार बदलने का अधिकार है

इस बारे में अधिक जानकारी के लिए मुझे किससे संपर्क करना चाहिए या यदि बाद में मेरे मन में कोई प्रश्न/शंका हो तो?

कोई जानकारी चाहिए तो संपर्क कर सकते हैं

डॉ. शशांक पवार

सदस्य सचिव, संस्था मानव आचार समिति।

संपर्क विवरण: फोन - 7773010099 और

ईमेल -ihecpgr@aiimsbhopal.edu.in

डॉ. ममता वर्मा,

प्रधान -अध्यापक नर्सिंग कॉलेज, एम्स भोपाल।

संपर्क विवरण: फोन- 919981540519,

ईमेल- प्रिंसिपल.नर्सिंग@aiimsbhopal.edu.

ANNEXURE 12

प्रतिभागी सूचना सहमति प्रपत्र(English/Hindi)

[PARTICIPANT INFORMED CONSENT FORM (PICF)]

इस अध्ययन के लिए प्रतिभागी का पहचान नंबरः …….....

Participant Identification Number for this Study: ……...

अनुसंधान का शीर्षकः "तृतीयक देखभाल अस्पताल, भोपाल में भर्ती प्रसव कराने वाली महिलाओं के बीच श्रम के पहले चरण के दौरान प्रसव पीड़ा की तीव्रता पर लम्बो-सैकरल क्षेत्र में गर्म संपीड़न की प्रभावशीलता का आकलन करने के लिए एक अध्ययन: एक यादृच्छिक नियंत्रित परीक्षण

1.Title of Project : **"A study to assess the effectiveness of warm compression at lumbo-sacral region on intensity of labor pain during first stage of labor among parturient women admitted in tertiary care hospital , Bhopal : a randomized controlled trial**

शोधकर्ता छात्र का नाम .. सुश्री शर्मिष्ठा पटेल

फोन नं:7435910118

Name of Student Investigator :Ms.Sharmistha Patel…… ……Tel No.(s) :

शोध मार्गदर्शक का नाम : डॉ.लिली पोडर

……..…….....

Name of Thesis Guide Dr.Lily Podder…….....

मैंने दिनांक 20.08.2022 के सूचना पत्रक संस्करण II में दिए गए सभी तथ्यों को सावधानीपूर्वक पढ़ लिया है/ मुझे अपनी भाषा में स्पष्ट रूप से विस्तारपूर्वक समझा दिया गया है, और मैंने तथ्यों को पूर्णतः समझ लिया है। मैं पुष्टि करता/ करती हूँ, कि मुझे सवाल पूछने के अवसर प्रदान किए गए। The contents of the information sheet version II dated 20 August 2022 that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

मुझे इस अध्ययन की प्रकृति एवं उद्देश्य और इसके संभावित जोखिमों / लाभों तथा अध्ययन की अनुमानित अवधि एवं अन्य प्रासंगिक जानकारी के बारे में विस्तारपूर्वक समझा दिया गया है। मुझे पता है कि इस अध्ययन में मेरी भागीदारी स्वैच्छिक है तथा मैं इस अध्ययन से किसी भी समय बिना कोई कारण बताए, अपना नाम वापस लेने के लिए स्वतंत्र हूं और नाम वापस लेने पर मेरी चिकित्सा देखभाल या कानूनी अधिकारों पर कोई प्रभाव नहीं पड़ेगा। The nature and purpose of the study and its potential risks/benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

मैं समझता/समझती हूं कि इस अनुसंधान में मेरी भागीदारी से मेरे बारे में एकत्र की गई जानकारी और मेरे चिकित्सीय दस्तावेजों के किसी भी भाग को एम्स के जिम्मेदार व्यक्तियों द्वारा ही देखा जाएगा। मैं इन व्यक्तियों को मेरे रिकॉर्ड प्राप्त करने की अनुमति प्रदान करता/ करती हूँ। I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIMS. I give permission for this individuals to have access to my records.

यदि प्रतिभागी बच्चा है तो उसकी मौखिक या लिखित सहमति प्राप्त की गई है। If participants is child, his/her verbal of written assent has been obtained.

मैं उक्त अध्ययन में भाग लेने के लिए सहमत हूं/I agree to take part in the above study.

_____

(प्रतिभागी के हस्ताक्षर / बांए अंगूठे का निशान) (Signature/Left Thumb Impression)
दिनांक/Date……स्थान/Place …….....

प्रतिभागी का नाम/Name of the participant…….....
पिता/पति/पत्नी का नाम /Son/Daughter/Spouse of…….
डाक का पूरा पता /Complete Postal Address ……....

अगर अशिक्षित हों / If illiterate.

सूचना पत्र को प्रतिभागी को पढ़ा और समझाया गया है और प्रश्न पूछने का अवसर दिया गया है। मैं पुष्टि करता हूं कि व्यक्ति ने स्वतंत्र रूप से अपनी सहमति दी है ।
The information sheet has been read and explained to the participant and given the opportunity to ask questions. I confirm that the individual has given consent freely.

कानूनी रूप से स्वीकार्य प्रतिनिधि या निष्पक्ष गवाह के हस्ताक्षर
Signature of Legally acceptable representative or impartial witness.
दिनांक/Date
एलएआर या निष्पक्ष गवाह का नाम / Name of LAR or impartial witness .
पता / Address :-

प्रमाणित किया जाता है कि उक्त सहमति मेरी उपस्थिति में प्राप्त की गई ।
This is to certify that the above consent has been obtained in my presence.

_____

छात्र शोधकर्ता के हस्ताक्षर दिनांक……. स्थान……
Signature of the student Investigator Date …… Place ……

कृपया ध्यान दें: सहमति प्रपत्र तीन प्रतियों में (1) रोगी के लिए, (2) शोधकर्ता, (3) संस्थान के लिए तैयार करें।

(छात्रों से अनुरोध है कि आसानी से समझ आने योग्य हिंदी अनुवाद स्वयं तैयार करें)

NB: Three copies should me made, for (1) Patient, (2) Researcher, (3) Institution (Students are requested to prepare the translation in simple understandable Hindi on their own.)

ANNEXURE 13

Master sheets

Coding sheet of control group.

PIN C	Age code	Education Code	Occupation code	Dietary Code	BMI CODE	GRAVIDA CODE	EXERCISE CODE	ANALGESIC CODE	ABORTION CODE	NATURE CODE	PREVIOUS CODE	MEDICAL CON.COD
1	1	4	7	2	2	1	4	2	1	2	4	5
3	1	4	7	1	2	1	4	2	1	2	4	5
5	2	2	1	2	2	1	1	2	1	1	4	5
7	2	2	7	2	2	1	4	1	1	1	4	5
9	3	2	7	1	3	2	4	2	2	1	1	5
11	2	3	7	1	2	1	2	1	1	1	4	5
13	2	4	7	2	2	2	4	2	1	2	1	5
15	3	4	7	2	2	2	4	2	1	1	4	5
17	1	2	7	1	2	1	4	2	1	2	4	5
19	2	2	7	1	3	1	1	2	1	1	4	5
21	2	2	7	1	2	1	4	2	2	2	4	5
23	1	2	3	1	2	1	4	2	1	1	4	5
25	3	3	7	1	2	2	4	2	1	1	1	5
27	2	2	7	1	3	1	1	2	1	2	4	5
29	2	4	7	2	2	1	3	2	1	2	4	5
31	3	2	7	1	2	2	4	2	3	1	4	5
33	2	2	7	1	3	1	4	1	1	2	4	5
35	1	5	7	1	2	1	4	2	1	1	4	5
37	2	5	7	2	2	2	4	1	1	1	1	5
39	3	2	7	1	3	2	4	2	1	2	4	5
41	2	2	7	2	2	1	4	2	1	1	4	5
43	2	3	4	1	2	1	4	2	1	2	4	5
45	1	6	7	2	2	1	4	2	1	2	4	5
47	3	6	7	1	2	2	4	1	1	1	1	5
49	2	2	7	1	2	1	4	2	1	1	4	5

Coding sheet of experimental group.

PIN E	Age code	Education Code	Occupation code	Dietary Code	BMI CODE	GRAVIDA CODE	EXERCISE CODE	ANALGESIC CODE	ABORTION CODE	NATURE CODE	PREVIOUS CODE	MEDICAL CON.COD
2	3	2	7	1	2	2	4	2	1	1	1	5
4	1	2	7	1	2	1	4	1	1	1	4	5
6	2	2	7	2	3	1	4	2	1	1	4	5
8	1	4	7	1	2	1	4	2	1	2	4	5
10	3	3	7	1	2	2	1	2	1	1	1	5
12	1	2	7	1	4	1	4	1	1	2	4	5
14	2	2	7	1	3	1	4	1	1	1	4	5
16	1	4	7	1	2	1	4	2	1	2	4	5
18	3	2	7	1	2	1	1	2	1	2	4	5
20	3	2	7	1	4	2	4	2	3	1	4	2
22	1	5	7	1	2	1	4	1	1	2	4	5
24	2	2	7	1	3	1	1	2	1	1	4	5
26	2	5	7	2	1	2	4	1	1	2	4	5
28	1	5	7	2	2	1	4	2	1	2	4	5
30	2	2	7	2	2	2	4	2	1	2	1	5
32	2	2	7	2	4	1	4	1	1	2	4	5
34	2	2	7	1	2	1	4	1	1	1	4	5
36	3	4	3	2	2	1	1	2	1	1	4	5
38	1	6	7	1	2	1	4	1	1	1	4	5
40	2	3	4	1	2	2	4	2	1	2	4	5
42	1	5	7	2	3	1	4	2	1	2	4	5
44	2	5	7	2	2	2	1	2	1	1	1	5
46	2	4	7	1	3	1	4	2	1	2	4	5
48	2	4	7	1	3	2	4	2	2	2	1	5
50	1	2	1	1	1	3	2	4	1	1	1	5

Annexure -14

Calibration certificate of lotion thermometer

CC-2689

Hi-Tech Laboratory & Services
(A House of Measurement & Calibration)

Shivani Complex, C-4, Vidya Vihar, Opp. Barkatullah University,
Bhopal- 462 026 M.P., India
Tel.: 0755 - 2410094, 4235738 Telefax. : 0755 - 2410094
Mobile: 094250 09513 web: www.htls.co.in
e-mail: htlsbpl@hotmail.com / info@htls.co.in

CALIBRATION CERTIFICATE

(Form No. HTLS/QF/7.8.1/01 (Amendment No. 00 Dated 1st January 2020)

ULR : CC268923100011329F	Thermal Calibration	Certificate Issue Date:	29.09.2023

Certificate No	Received On	Received Condition	Calibration On	Calibration Due	Page No.
HTLS/23/PSB/883.01	27.09.2023	working	28.09.2023	27.09.2024 (As per customer requirements)	1 of 1

1)a. Calibrated for:
Miss Patel Sharmisthaben Bhartbhai,
Room No-503 , PG Transit Hostel ,
AIIMS , Saket Nagar
Bhopal - 462020 (M. P)

b. Name of Equipment /Instrument :
Glass Thermometer (Lotion)

c. Calibration Location: At Lab

2) Description & Identification of Equipments / Instruments Under Calibrations (EUC*):

Manufactured by	Immersion	Serial No.	Type	Identification No.
Dimple	76 mm	---	---	PSB/GT/01

Range	Least Count	Calibrated Range	Declared Accuracy	Location
0 to 360 °C	2 °C	0 to 302 °C	±2 °C	---

3) Standards/ Calibrator & Measuring Equipments Used :

Standards Used	Make / I.D.No.	Traceability Certificate No.	Calibrated By	Validity
High Precision Digital Thermometer With RTD (PT - 100)	Yudian & AI-5600 / HTLS/DT/01	TL/022/1215.1.1	NABL : CC2840	04.11.2023
with Low Temp.Liqued Calibration .Bath (-80°C to Ambent) , Oil Temp. Bath (Ambent to 250°C) & High Temp. Bath				

4) Principle /Methodology of Calibration & Procedure :
Methodology adopted for Calibration is as per HTLS Procedure NO.HTLS/CP/TH-01 which is based on IS :4825-1982 & IS : 6274

5) Calibration Results:

Sl. No.	Unit	EUC Value	Standard Value (Average)	Deviation	Expended Uncertainty (±)
a.	°C	0	-0.15	0.15	1.12
b.	°C	50	49.83	0.17	
c.	°C	100	99.80	0.20	
d.	°C	202	200.65	1.35	
e.	°C	302	300.53	1.47	

The values have been rounded off as per IS:2-1960(wherever applicable).
Expended uncertainty reported is at approx 95% confidence level with K=2.
Temperature scale :International Temperature Scale -1990.

6) Environmental Condition's): a) Temperature: 25±2°C b) Humidity: 60±15%

7) Calibration Status & Remark :

a. A Calibration Sticker has been affixed on EUC*.
b. The Glass Thermometer has been calibrated and found to be within accuracy limit .
c. Refer to report before use. Under NABL scope upto 250°C.

**********END OF THE CERTIFICATE**********

Calibrated by:		Approved by :	
ASAD AHMAD Techanical Manager		SANJAY BAIS Quality Manager	

Hi-Tech Laboratory & Services BHOPAL